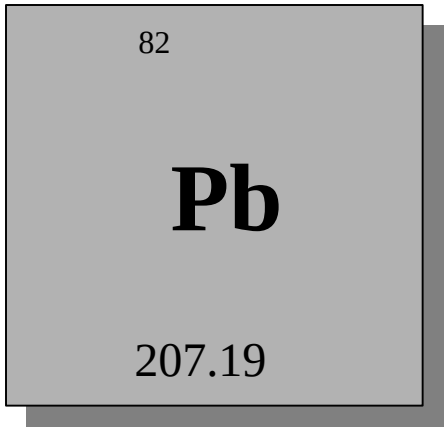
California Environmental Protection Agency

Air Resources Board

Risk Management Guidelines for New, Modified, and Existing Sources of Lead



Stationary Source Division
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Risk Management Guidelines for New, Modified and Existing Sources of Lead

Prepared By:

Carol McLaughlin

With Assistance From:

Renèe Coad
Marie Kavan
Hien Tran
Skip Campbell

Reviewed and Approved By:

Daniel E. Donohoue, Chief, Emissions Assessment Branch
Tony Andreoni, Manager, Process Evaluation Section

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Acroymns and Abbreviations

AERMOD	American Environmental Regulatory Model
APCO	Air Pollution Control Officer
ARB	Air Resources Board
ASTM	American Standards and Testing Methods
BLL	Blood Lead Level
CAPCOA	California Air Pollution Control Officers Association
CDC	Centers for Disease Control and Prevention
CLPPB	Childhood Lead Poisoning Prevention Branch
DHS	Department of Hazardous Substances
District	Air Pollution Control District or Air Quality Management District
DTSC	Department of Toxic Substance Control
GM	Geometric Mean
GSD	Geometric Standard Deviation
H&SC	California Health and Safety Code
HRA	Health Risk Assessment
HUD	Department of Housing and Urban Development
IEUBK	Integrated Environmental Uptake BioKinetic
ISCST3	Industrial Source Complex - Short Term, version 3
km^2	squared kilometer
ln	natural logorithm
MEA	Maximum Exposure Area
MECR	Maximum Excess Cancer Risk
MOC	Maximum Offsite Concentration
NTIS	National Technical Information Service
OEHHA	Office of Environmental Health Hazard Assessment
REL	Relative Exposure Limit
RRAP	Risk Reduction Audit and Plan
SCREEN3	Screening version of the ISCST3 model
SRP	Scientific Review Board
TAC	Toxic Air Contaminant
T-BACT	Toxic Best Available Control Technology
µg/dL	microgram per deciliter
$\mu g/m^3$.	microgram per cubic meter
U.S. EPA	United States Environmental Protection Agency

Risk Management Guidelines for New, Modified, and Existing Sources of Lead

I. Introduction

A. Purpose of the Guidelines

In April 1997, the Air Resources Board (ARB or Board) identified inorganic lead as a toxic air contaminant (TAC). The primary basis for the identification was the health impacts associated with neurodevelopmental impairment in children. Other potential health effects identified were increased blood pressure in adults and cancer.

Lead is unique among the toxic air contaminants that the Board has identified in several ways. First, children are particularly susceptible to levels of lead in their blood due to exposure to lead. Second, the chronic non-cancer effects are related to blood lead levels as opposed to ambient air concentrations. These blood lead levels reflect current and past exposure from a number of sources; air emissions may only be a small part of the total exposure. Third, based on recommendations of the Office of Environmental Health Hazard Assessment (OEHHA) and the Scientific Review Panel (SRP), the Board did not identify a threshold level for acute or chronic non-cancer health effects due to exposure to lead air concentrations. Threshold levels are levels below which no adverse health effects are expected to occur. These levels are typically expressed as ambient air concentrations and are referred to as Reference Exposure Levels (REL). All previous estimates of non-cancer effects for identified toxic air contaminants were based on the use of an REL. For lead, no REL was given.

At the hearing, the Board recognized the challenges of risk management of inorganic lead because of the unique nature of the identification. Therefore, the Board directed the staff to work with affected parties, OEHHA, and the air pollution control and air quality management districts (districts) to develop risk management guidelines. As a result, we have prepared these Risk Management Guidelines for New, Modified, and Existing Sources of Lead (Guidelines).

In general, these Guidelines are designed to provide assistance to the districts in making risk management decisions for new, modified, and existing stationary sources of lead. We recognize that individual districts may need to tailor these Guidelines to their own specific air quality situations and needs. As such, these Guidelines should be viewed only as a framework for making risk management decisions at the local level.

These Guidelines fulfill the need to have a new procedure for making risk management decisions for exposure to lead. Specifically, the Guidelines:

- promote a consistent site-specific risk assessment approach to evaluating potential lead risk by establishing step-by-step procedures for quantifying cancer health risks and non-cancer neurodevelopmental impairment health risks in children. These procedures are based on the risk assessment information used in the Board's proceeding for the formal identification of lead;

- provide guidance on determining when to require application of the toxic best available control technology (T-BACT);

- provide guidance on making decisions concerning the issuance of permits for new and modified stationary sources; and

- provide guidance to the districts in setting public notification, significant risk, and unreasonable risk levels for the Air Toxics "Hot Spots" Information and Assessment Act of 1987 (Hot Spots Program).

The Guidelines complement existing risk assessment and risk management guidance developed by the California Air Pollution Control Officers Association (CAPCOA) and the ARB (ARB, 1993, CAPCOA, 1993). OEHHA is developing new risk assessment guidelines, pursuant to the provisions of Senate Bill 1731. When the OEHHA guidelines become effective, they should be used where appropriate.

B. Development of the Guidelines

On June 17 and 20, 1997, we held initial public workshops in Los Angeles and Sacramento, respectively, to acquaint interested parties with the nature of the project and to invite them to participate in a workgroup that would assist us in developing the Guidelines. Subse-quently, the workgroup was formed and consisted of representatives of industry, several districts, the Department of Health Services, the Department of Toxic Substances Control, and OEHHA. In addition, several other organizations were sent copies of all correspondence. These organizations included the Natural Resources Defense Council and the United States Environmental Protection Agency (U.S. EPA).

The workgroup met seven times following the initial public workshops. We developed and circulated several of the draft Guidelines to seek comments on the technical approach and on the practical ability to implement the Guidelines on the local level. The Guidelines attempt to balance the uncertainty of the risk assessment process with the need to have a simple and direct method for quantifying the health effects as a basis for risk management decisions. The workgroup was not asked to reach a consensus on these Guidelines but rather individual members

submitted their comments during the public workshops. The workgroup has been invaluable in providing significant comments that have greatly assisted us in understanding the issues and concerns associated with the risk management process for lead and helping to develop a relatively simple approach for making risk management decisions.

We released the guidelines for public comment on September 6, 2000. On October 3, 2000, we held a public meeting to discuss the guidelines and comments we had received. We have addressed the public comments to the extent possible in this final version.

C. Structure of the Guidelines

The Guidelines are presented as three Chapters, with a series of technical appendices. Chapter I presents a brief introduction to the issues associated with lead risk management. Chapter II provides instructions for conducting site-specific risk assessments for the non-cancer and cancer health effects of lead. Chapter III provides specific risk management guidance for local air district permitting and Hot Spots Programs.

In Chapter II, we begin by presenting a simplified, screening-level approach to evaluate non-cancer risks using the neurodevelopmental risk as a surrogate. The approach uses conservative health-effect assumptions; therefore, projects that pass the criteria in this approach are very unlikely to pose a health risk. The rest of the chapter provides more detailed step-by-step approaches for estimating neurodevelopmental and cancer health risk.

For estimating the neurodevelopmental effect in the detailed analysis, we provide three tiers of analysis in order of increasing complexity and data requirements. Tier I is a screening level approach and uses default assumptions to estimate the potential health risk. On the other hand, Tier III is a more rigorous approach that uses site-specific blood lead level distributions and other site-specific information to estimate the potential health risk. We have used the tiered approach to accommodate the need for a simple screening tool, as well as a more refined tool to address particular situations. We have not provided a tiered approach for cancer risks as this analysis should be done consistent with existing procedures for assessing cancer risks.

The risk assessment information provided by OEHHA includes the tools to assess cardiovascular risk. However, we are not providing detailed instructions for estimating cardiovascular effects. We were concerned about the uncertainty in the dose-response relationship at blood lead levels one-half to one-third those seen in the studies on which the OEHHA assessment was based. After evaluating the options for making an assessment of cardiovascular effects, we concluded that our risk management recommendations based on neurodevelopmental effects were sufficiently health protective for adults and additional control for cardiovascular risk was

not justified. Therefore, we elected to omit the calculation of cardiovascular risk in these Guidelines.

In Chapter III, we present suggested levels for risk management decisions. As in Chapter II, we begin by presenting risk management levels for the simplified screening-level approach, followed by a presentation of risk management levels to use for the more detailed analyses. Specifically, we suggest trigger levels for requiring T-BACT, as well as suggested levels for approving and denying permits for new and modified sources. We also include suggested levels for public notification, significant risk, and unreasonable risk for districts to use in implementing the Hot Spots Program. Again, we emphasize that the risk management decision levels are only suggestions. The districts must make their own determinations in recognition of local issues and concerns.

In addition, the Appendices to this report provide much of the basis and rationale for these Guidelines. The reader is encouraged to read the Appendices. A brief description of each Appendix follows.

Appendix A discusses lead levels in the air and in blood, and trends in air lead concentrations and blood lead over the last few years.

Appendix B gives detailed instructions for retrieving information from the U.S. Census. The process of estimating neurodevelopmental risk outlined in these Guidelines uses census data. The census data can be accessed over the internet or from one of the Census State Data Centers listed in Appendix B.

Appendix C gives valuable background to the process for estimating neurodevelopmental risk. It also gives the basis for default values incorporated in the estimate of neurodevelopmental risk.

Appendix D discusses models used to relate air lead concentrations to blood lead. The non-cancer health effects are related to the blood lead levels. There are two ways to estimate blood lead levels from air lead concentrations. One has been used to derive a general factor that applies where the lead concentrations in the environment are unknown. The other takes into account lead concentrations in the environment and predicts the blood lead levels.

Appendix E outlines the procedure to follow when making arithmetic calculations with logarithmic data such as blood lead levels.

Appendix F provides an alternate approach to calculating neurodevelopmental risk for activities that will be emitting lead for less than 30 days.

Appendix G provides tools for evaluating sample size with regard to level of confidence and margin of error in blood lead sampling programs.

Appendix H discusses the risk management levels and the studies, reasoning, and regulatory precedents we considered in choosing levels to recommend to the districts.

Appendix I discusses findings upon which the district may base a decision to permit a source when risks are higher than the approvable level.

Appendix J briefly reviews the existing regulatory structure for airborne lead.

Appendix K contains the form for reporting to the Childhood Lead Poisoning Prevention Branch when a Tier II or Tier III study is planned.

D. Uncertainty in Health Risk Assessment

When lead was identified as a toxic air contaminant, the Board acknowledged that uncertainty exists when dealing with the quantitative correlation of potential health effects and exposure. At the hearing, the Board approved a preface to the identification report that discusses uncertainty. In essence, the preface indicates that the Board acknowledges and agrees with OEHHA and SRP that uncertainty exists when dealing with the quantitative correlation of potential health effects of exposure to low concentrations of inorganic lead[1]. The Board directed that, as risk management guidelines are developed, the uncertainties be taken into account and the science updated as appropriate. It should be noted that the preface was not reviewed or accepted by the SRP and was not intended to modify the SRP's findings on the inorganic lead report. The preface can be found in its entirety in the report titled "Proposed Identification of Inorganic Lead as a Toxic Air Contaminant, Staff Report/Executive Summary, April 24, 1997." The report can be accessed on the ARB's website at www.arb.ca.gov.

There is usually some degree of uncertainty associated with the process of risk assessment. This uncertainty arises from both the scientific process of risk assessment and the available data. There are two general areas of uncertainty: 1) uncertainty in the estimation of potency, and 2) uncertainty in the calculation of exposure.

[1] In the preface, 'low levels of air concentrations of inorganic lead' was defined as the statewide population-weighted average estimated to be 0.02 micrograms per cubic meter based on data collected in 1994-95. As shown in Appendix A, the statewide annual average has declined from 0.052 micrograms per cubic meter in 1990 to 0.017 micrograms per cubic meter in 1997. For additional information about air lead concentrations and trends, see Appendix A.

Effects of exposure to more than one carcinogen or toxicant are also not quantified in the risk assessment. Many examples of additivity or synergism (effects greater than additive) are known. For chemicals which act synergistically, the risk assessment could underestimate the risks. Some chemicals may have antagonistic effects (lessen the toxic effects produced by another chemical). For chemicals which act antagonistically, the risk assessment could over-estimate the risks. Additionally, there may be chemicals which pose health risks but are not considered in a given risk assessment for a number of reasons, including lack of information on toxicity; this could result in underestimating the risk.

The uncertainty in risk assessments is difficult to quantify, and, in most cases, the quantification of uncertainty is itself uncertain. The risk levels generated in a risk assessment are useful as a yardstick to compare one source with another and prioritize concerns. Consistent approaches to risk assessment are necessary to fulfill this function. This is one of the purposes of developing these Guidelines. Risk assessment results should not be construed as the expected rates of disease in the exposed population but are merely estimates of risk, based on current knowledge and a large number of assumptions.

1. Uncertainty in Estimates of Potency

There are three primary sources of uncertainty in estimating potency: 1) uncertainty in extrapolating dose/response estimates used to quantify health effects from animals to humans, 2) uncertainty in extrapolating from high doses to low doses, and 3) uncertainty in confounding factors that could obscure the actual magnitude of an association between exposure to the pollutant and an adverse health effect. In the case of the non-cancer neurodevelopmental effects of lead, there was no animal-to-human extrapolation and only limited high dose-to-low dose extrapolation in the studies used to develop the potency factors. Many of the studies were undertaken at current air or blood lead levels. The potential for confounding exists but the number and consistency of the studies indicate the health effects cannot be explained away by potential confounding and real health effects exist. Nevertheless, to illustrate the uncertainty and following general scientific guidelines, the OEHHA commonly calculates the 95 percent confidence intervals around their estimates of potency. These are shown in the "Technical Support Document, Proposed Identification of Inorganic Lead as a Toxic Air Contaminant, Part B Health Assessment" March 1997 (ARB, 1997), located on the ARB web site at www.arb.ca.gov.

2. Uncertainty in Estimates of Exposure

There are two primary sources of uncertainty in estimating exposure: 1) uncertainty in estimating or monitoring ambient concentrations, and 2) uncertainty in estimating baseline blood lead levels. Sources of uncertainty in estimating the ambient concentrations include the accuracy of the emission estimates, the quality of the meteorological data, and the accuracy of the dispersion model. Uncertainty in estimates of exposure based on monitoring data relate to measurement variability, sampling frequency, and siting issues. Sources of uncertainty in baseline blood

lead levels include other sources of exposure, metabolism, diet, behavior, sensitivity, and body burdens. There is a large degree of individual variability among humans even when the environmental concentrations are the same.

3. How Uncertainty is Addressed in the Guidelines

We have addressed uncertainty in these Guidelines in three ways. First, we estimated the neurodevelopmental risk to the children in a neighborhood as opposed to estimating the risk for a child or children that may be living in the location where the air dispersion model predicts the highest concentration. This is appropriate because the neurodevelopmental risk is based on the percentage of the population expected to have blood lead levels of concern. While we can calculate the probability of having a blood lead level of concern for an individual child, we can not have a high level of confidence in it if we do not know how much lead is in the soil, dust, water and other sources of exposure in that particular child's environment.

Second, we provided two exposure scenarios for the assessment of neurodevelopmental risk when default values are used for baseline blood lead levels. We believe it is prudent to limit increases in emissions of lead to the air for populations with greater potential for exposure from sources other than the source being evaluated. Thus, we have defined criteria for a high exposure scenario and selected baseline blood lead statistics to reflect that higher than average potential for exposure.

Finally, we provided a tiered structure which allows sources to chose from three increasingly site-specific options for estimating baseline blood lead levels.

II. Site-Specific Health Risk Assessments

This Chapter provides guidance on how to do a site-specific health risk assessment for lead. The health effects addressed are non-cancer and cancer effects. We are using the estimates of risk based on non-cancer neurodevelopmental impacts on children as a surrogate for both non-cancer neurodevelopmental and cardiovascular risks to adults. The information generated in this chapter is used with the information in Chapter III to make risk management decisions.

We begin by presenting a simplified screening-level approach to evaluate the non-cancer risks using the neurodevelopmental risks as a surrogate. This simplified approach is based on air concentrations and can only be used if the source is not located in a high exposure area. It is offered as a more conservative screening tool that should apply to most sources. It is an easier alternative to the more detailed approach for assessing neurodevelopmental effects. We then present more detailed approaches to specifically evaluate neurodevelopmental effects.

Finally, we present basic information on conducting a health risk assessment for cancer. Cancer health effects are evaluated in accordance with established procedures. These procedures require that the individual cancer risk from each carcinogen be summed to estimate the total facility cancer risk.

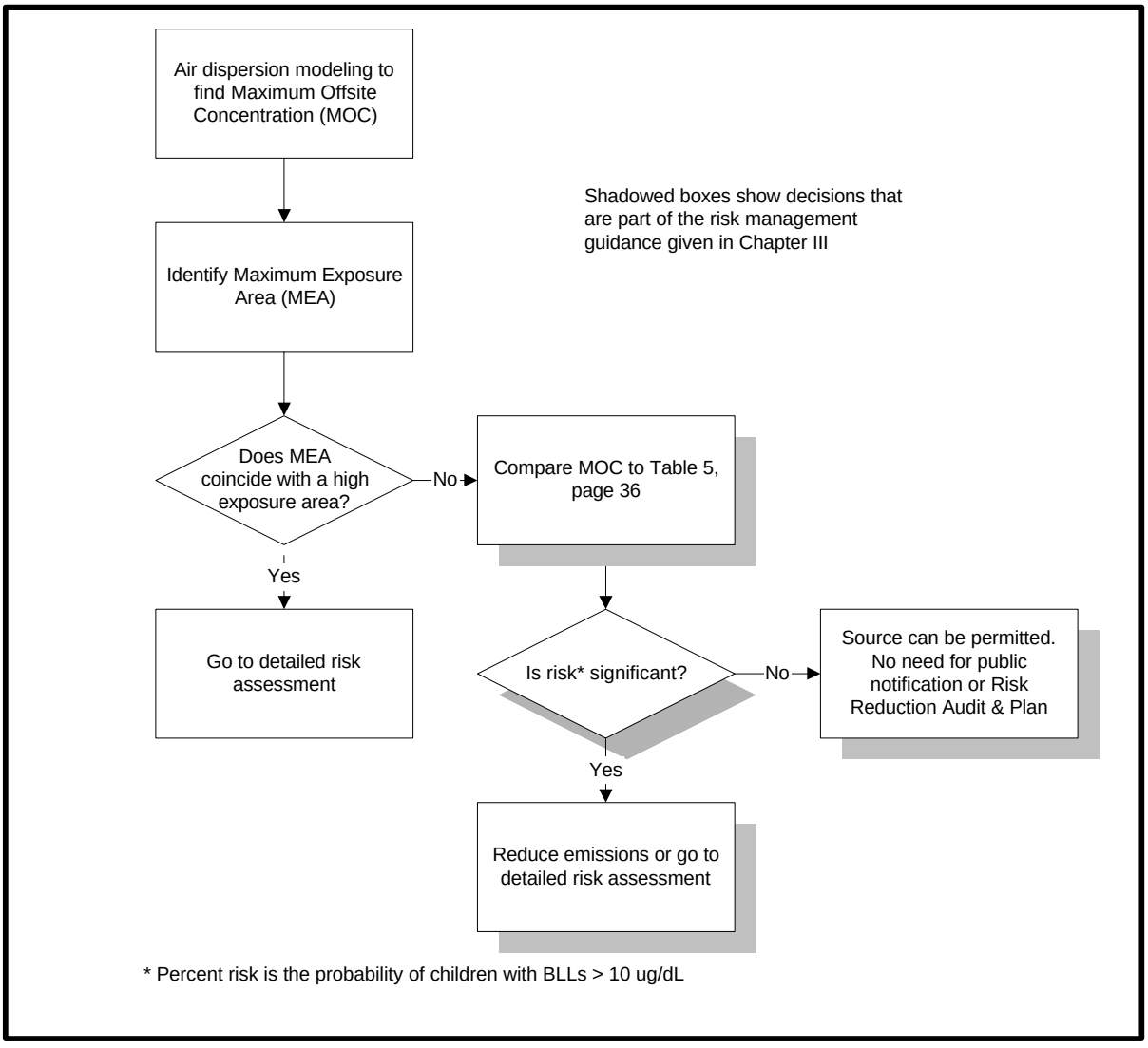
In general, we recommend that a facility discuss the risk assessment approach and reach a consensus on the approach with the district in advance. Note that the district and OEHHA must approve the risk assessments done for compliance with the Air Toxics "Hot Spots" Program.

In order to estimate health risk, you need an estimate of exposure and an estimate of potency. The estimate of exposure is based on estimates of emissions. Air dispersion modeling is then used to estimate the amount of lead in the air. The OEHHA and the SRP have approved estimates of potency for lead in the report titled, "Technical Support Document, Proposed Identification of Inorganic Lead as a Toxic Air Contaminant Part B Health Assessment," March 1997 (ARB, 1997), found on the ARB website at www.arb.ca.gov.

A. Simplified Approach for Assessing Non-Cancer Risks

In this section, we describe a simplified approach for assessing neurodevelopmental risks. This simplified approach is being proposed to provide a simple and less resource-intensive procedure for evaluating the non-cancer effects of lead exposure. This approach cannot be used in exposure areas with a high potential for existing lead exposure. However, we expect that the approach can be used for a majority of the sources in the State. Note that cancer risks must still be evaluated in accordance with procedures specified in Section D. Figure 1 is a flowchart of the simplified process discussed in this section.

Figure 1 Simplified Approach



This simplified approach is based on a conservative estimate of the air concentrations associated with the facility. These concentrations would then be compared to appropriate risk management levels presented in Chapter III, Section D. These risk management levels take into account the direct exposure from the facility and the exposure due to background concentrations in the environment. This simplified approach uses a 30-day maximum offsite concentration (MOC) to determine a maximum exposure area (MEA). The MEA is the area surrounding the MOC, equivalent to the size of a square area with side lengths of 1 kilometer. The simplified approach is conservative compared to the detailed approach for sources in an average exposure area. It is not conservative enough to be used for a source in a high exposure area. Consequently, to use this approach, a source would determine air lead concentrations and, based on the

dispersion modeled location of the MOC and census data, assess whether the MEA coincides with a high exposure census tract. If not, the source would compare the monitored or modeled air concentrations to the levels listed in Chapter III (Table 5 on page 36 for the simplified approach). A source that exceeded these levels could go on to do the more detailed assessment. In this section, we outline the steps for the simplified approach.

Step 1: Estimate the 30-Day Maximum Offsite Concentration and Location of the Maximum Exposure Area

After the lead emissions from a facility have been determined, an air quality dispersion model is used to estimate the value and location of the maximum offsite air concentration, in micrograms per cubic meter ($\mu g/m^3$), over a 30-day averaging time. The location of the maximum offsite air concentration will be used to identify the maximum exposure area (MEA). The MEA is used in Step 2 to determine whether a source can use this simplified approach for assessing non-cancer risk.

We recommend using the air dispersion modeling guidance in the OEHHA Risk Assessment Guidelines, Part IV (OEHHA, 2000). The Risk Assessment Guidelines recommend using SCREEN3 as a screening model. The SCREEN3 model uses a universal set of meteorological inputs to estimate the maximum one hour concentration. The maximum one hour concentration is then multiplied by a factor, 0.3, recommended by the U.S. EPA (U.S. EPA, 1992) to estimate the 30-day average. The ISCST3 model is recommended where a more refined analysis is desired and site-specific data are available. The ISCST3 model uses locally measured meteor-ology to estimate the one hour concentration for each hour of the year. The maximum one hour concentrations can be extracted and averaged over each consecutive 30-day period to find the highest consecutive 30-day average. Both the SCREEN3 and ISCST3 develop estimates of air concentrations and can be used to estimate the spatial distribution of concentrations. ISCST3 can create an array of receptors that can range from coarse scale (e.g. 1 kilometer spacing) to fine scale (e.g. 100 meter spacing), or consist of selected points. Currently the U.S. EPA is evaluating the ISC-PRIME and AERMOD models, and can be considered for future use upon the U.S. EPA's approval. The MEA is a 1 square kilometer area centered on the MOC and may be a square or a circular area.

Instead of using dispersion modeling to estimate ambient lead concentrations, local air monitoring data may be acceptable to characterize the air concentration for risk assessment purposes. For the district to approve monitoring data for this use, they would need to evaluate the quality of the monitoring data for this purpose. Among the factors to consider, would be the representativeness of the monitoring to exposure. This would include evaluating the frequency of sampling and analysis, seasonal and meteorological variability in ambient concentrations and the adequacy of the data to characterize the contribution from the facility. For instance, a 30-day average based on sampling every sixth day (if all samples were analyzed) is only 5 samples and may not be adequate to characterize exposure. Isolating the contribution of the facility is even

more difficult. In some cases, a direction is designated "upwind" based on the predominant wind direction and considered to be the background concentration. However this "background" concentration can include emissions from the facility if the wind direction reverses for some part of the day or night. Under these circumstances, subtracting the "upwind" concentrations would underestimate the actual exposure. Multiple monitoring locations may be required to characterize emissions over an area such as the MEA.

Step 2: Evaluate Eligibility

A source may use this simplified approach if the MEA does not overlap any census tracts with a high potential for existing exposure. A census tract with a high potential for existing exposure is defined as a census tract where the median year of construction for housing is 1960 or earlier and more than 30 percent of the population has an income less than 1.25 times the poverty level. A discussion of the basis and rationale for these criteria for defining a high exposure area can be found in Appendix C. If the source is not eligible to use the simplified approach, the detailed procedure shown in Section B should be followed.

To obtain the needed census data, you must identify the census tract number(s) that fall within the MEA. The location of specific census tract(s) can be obtained from a Census State Data Center. The location of these Census State Data Centers is presented in Appendix B.

Using the census tract number(s), you must obtain the following data from the U.S. Census Bureau website or the Census State Data Center: (1) the median age of housing for the census tract, (2) the ratio of income in 1989 to poverty level[1] (for persons for whom poverty status is determined). The ratio of income to poverty level will include nine categories ranging from less than 0.50 to 2.00 and over. To calculate the fraction of the population with an income less that 1.25 times the poverty level, you will need to sum the number of people in the 4 categories with ratios less than 1.25 and divide by the total number of people in all nine categories. Multiply this fraction by 100 to calculate the percentage you will use with the median age of housing to determine if the MEA is in a high exposure area.

You can obtain census data from the web site of the U. S. Census Bureau at http://homer.ssd.census.gov/cdrom/lookup or from one of the Census State Data Centers listed in Appendix B. Appendix B provides examples and detailed instructions for obtaining this information.

[1] The ratio of 1989 income to poverty level is given for the 1990 census data. We anticipate an equivalent statistic will be given when the 2000 census data is released.

Step 3: Compare the Air Concentrations to Risk Management Levels

This simplified approach is completed by comparing the maximum offsite air concentration determined in Step 1 to the recommended risk management levels for non-cancer health effects given in Chapter III (see Table 5, page 36), Section D, of these Guidelines. The district may choose to use different risk management levels than those recommended in Chapter III.

B. Detailed Approach for Estimating Non-Cancer Risks

In this section, we describe procedures to use for estimating non-cancer health risk from exposure to lead. This detailed approach is based on an assessment of neurodevelopmental risk. The most significant factor in assessing neurodevelopmental risk is the blood lead level (BLL) distribution in the population. Once the BLL distribution is determined, standard statistical methods can be used to calculate the percentage of the population expected to have a BLL greater than or equal to ($\geq$) a specified BLL expressed in micrograms per deciliter of blood (µg/dL).

The BLL distribution will consist of two components: (1) the baseline BLL distribution due to all sources of exposure; and (2) the exposure due to emissions from a facility. We have provided three tiers of analysis that can be used to determine baseline BLL distributions for estimating risk.

Tier I is a default approach that requires minimal site-specific information on concentrations of lead in environmental media other than air. Tier I uses two default BLL distributions, one for a high exposure scenario and one for an average exposure scenario. The default baseline BLL distribution for each of the exposure scenarios is based on a review of neighborhood and community blood lead studies. The studies and the basis for their selection as default BLL distributions are discussed in Appendix C.

Tier II develops baseline BLL distributions from site-specific estimates of lead levels in soil, dust, water, and/or food and uses the U.S. EPA Integrated Exposure Uptake Biokinetic (IEUBK) model. The IEUBK model calculates the probability of an individual exceeding a specified BLL given the site specific inputs. The aggregate of the individual risks is used to estimate the risk in the maximum exposure area. The IEUBK model is discussed in Appendix D.

Tier II involves activities that would be considered a lead hazard evaluation and would therefore be regulated under Title 17, California Code of Regulations, Division 1, Chapter 8; Accreditation, Certification, and Work Practices for Lead Based Paint and Lead Hazards[2]. This

[2] Copies of this regulation can be obtained from the Department of Hazardous Substances (DHS) Childhood Lead Poisoning Prevention Branch (CLPPB) internet address www.dhs.ca.gov/childlead, or by calling CLPPB at (510) 622-5000 or the lead related construction hotline at (800) 597-5323.

means that workers doing the sampling would need to be certified and the work would need to be carried out in compliance with work practice standards specified in Article 16.

Tier III involves actual blood lead sampling to define the baseline BLLs. In Tier III, the facility would conduct BLL testing to establish a site-specific BLL distribution.

We are recommending the neurodevelopmental risk be calculated as the probability of children in an affected exposure area having a BLL $\geq$ 10 µg/dL. This is because the Centers for Disease Control and Prevention (CDC) has identified 10 µg/dL as the BLL of concern and recommends that the prevention of BLLs $\geq$ 10 µg/dL should be the goal of all primary prevention activities. This probability would be compared to the risk management levels in Chapter III to determine whether facilities are subject to certain regulatory provisions. For some purposes, we also recommend consideration of the portion of the blood lead contributed by an individual facility.

1. Tier I - Estimating Neurodevelopmental Risk From Default Blood Lead Levels

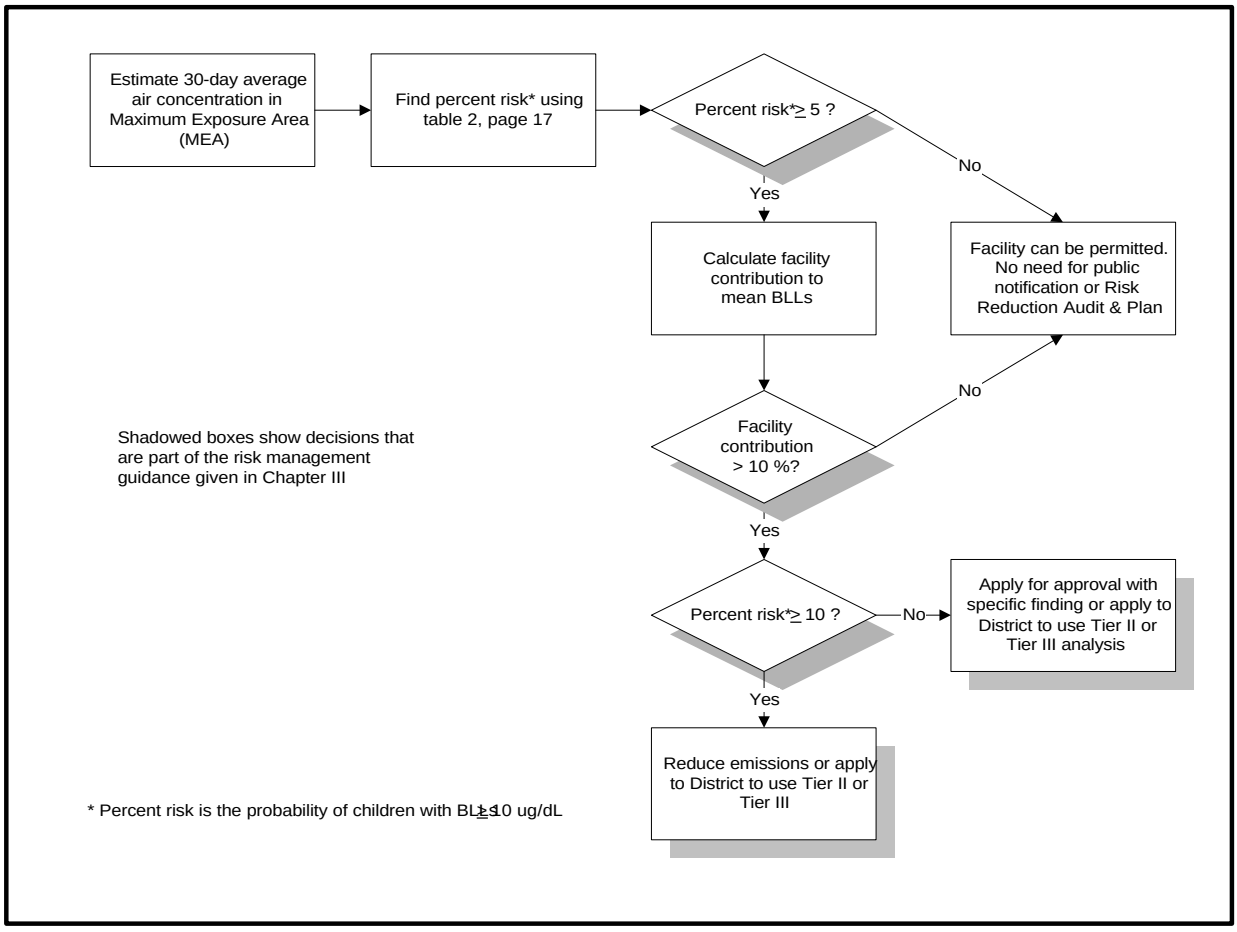
This section describes how Tier I can be used to derive an estimate of the probability that children in the maximum exposure area will have BLLs $\geq$ 10 µg/dL. In Tier I, we use default BLL distributions for two exposure scenarios: a high exposure scenario and an average exposure scenario. The high exposure scenario represents children with a higher likelihood of exposure to lead from paint. The baseline BLL distribution for the high exposure scenario has been chosen to account for this higher exposure. The average exposure scenario represents children with a more common variety of exposures.

In general, the approach involves estimating the 30-day average air concentration for the maximum exposure area, identifying the exposure scenario to determine the baseline BLL, and then estimating the probability of BLLs $\geq$ 10 µg/dL due to the facility emissions. Figure 2 is a flowchart of the steps in the detailed approach using Tier I.

Step 1: Estimate the 30-Day Air Concentration in the Maximum Exposure Area

The 30-day air concentration is calculated in the same manner outlined in Section A, Step 1. However, instead of using the maximum offsite air concentration as in Section A, Step 1,

Figure 2 Detailed Approach using Tier I Methods



the average ambient air concentration in the MEA is used.[3] If adequate monitoring data are available (see Step 1, Page 10), they may be used instead of the data obtained from the dispersion model.

The MEA is the one kilometer square area centered on the predicted point of the maximum 30-day offsite air concentration of lead. Any change in the emissions or release para-meters, as might occur with the installation of air pollution control equipment, will require revised air dispersion modeling. When averaging the air concentrations, omit any air concen-trations within the boundaries of the source being evaluated.

[3] This modeling method, using an average concentration across the area of exposure, is unique to assessing the non-cancer neurodevelopmental health effects of lead and should not be used to model impacts from cancer and other non-cancer health effects. Modeling of health risks due to other toxics should be accomplished according to OEHHA Risk Assessment Guidelines, Part IV (OEHHA, 2000).

The calculation of risk for the MEA based on the average air concentration does not give a complete picture of the total potential risk because, as the lead is dispersed in the air, large numbers of people are exposed to lower concentrations. However, we believe this provides a reasonable basis for risk assessment and risk management. We make this recommendation because the air lead is affecting the BLL distribution of the whole MEA. Many factors affect the BLL distribution in children and a given level of exposure may affect individual children in different ways. Given the complexity of the exposure picture, we believe this approach most effectively describes the potential risk when effects are based on BLLs $\geq$ 10 µg/dL.

Step 2: Identify Whether a Non-Residence Exposure Correction is Appropriate

If there are residences in the MEA, the estimated 30-day average lead concentration calculated in Step 1 should be used for evaluating risk. If there are no residences in the MEA and the only exposure in the MEA is to non-residents, an adjustment may be made for reduced hours of exposure under certain conditions. For example, if the source is emitting for 24 hours a day and 7 days a week, an adjustment in air concentration may be made to account for the presence of an offsite worker for 8 hours a day, 5 days a week. In such a case, for a facility operating 24 hours a day and 7 days a week, the adjusting factor would be (8/24)*(5/7) = 0.238 if all the offsite workers are only present in the MEA for 8 hours a day and 5 days a week. This adjustment factor would be multiplied by the 30-day average air concentration estimated using dispersion modeling in Step 1 and the resulting adjusted concentration would be used in all later steps.

Step 3: Determination of the Default Baseline Blood Lead Level Distributions

We have designated criteria for identifying areas where the potential for existing expo-sure is high. These criteria are based on census data as explained in Section A, Step 2. To select the appropriate exposure scenario, you will need to obtain and use census data. You can obtain census data from the census bureau web site at http://homer.ssd.census.gov/cdrom/lookup or from one of the State census data centers listed in Appendix B.

First, identify the census tract number(s) of the MEA. The location of specific census tracts can be mapped on the census bureau's web site or can be obtained from the State Data Centers. Next, find the median age of housing for the census tract(s) and the ratio of income in 1989[4] to poverty level. The income to poverty level is displayed in the census data-base as the number of persons in each of 9 categories ranging from less than 0.50 to 2.00 and over. As explained in Section A, Step 2, you will need to calculate the percentage with incomes less than 1.25 times the poverty level within the MEA. See Appendix B for examples and detailed instructions for obtaining this information.

[4] The ratio of 1989 income to poverty level is given for the 1990 census data. We anticipate an equivalent statistic will be given when the 2000 census data is released.

In the high exposure scenario, the mean BLLs will be higher as a result of exposure to higher levels in dust and soil and typically results from the use of lead in paint. You would use the high exposure scenario if the mean age of housing is 1960, or older, and more than 30 percent of persons for whom poverty status is determined have a ratio of income to poverty level less than 1.25.

The BLL distribution for this exposure scenario is established by using two statistical parameters: (1) the geometric mean (GM); and, (2) the geometric standard deviation (GSD). The GM and GSD are necessary to calculate the percentage of the population expected to have BLLs $\geq$ 10 µg/dL. The GM and GSD are statistical terms used to describe a log-normal distribution such as blood leads. They are used with other statistical tools to estimate the fraction of blood leads that would be at or over a specific level. The GM describes the midpoint of the distribution and the GSD describes the spread. For example, in two sets of observations {1,3,3,3,4,5} and {1,2,3,3,5,6} the GM is the same but the GSD is greater for the second set because of the greater variability in the distribution.

To determine the GM and GSD for the high exposure scenario, we evaluated a number of studies of neighborhood and community BLL distributions and selected the GM and GSD from Area A in the Butte, Montana study (GM = 3.69 µg/dL, GSD = 1.84). As discussed in Appendix C, this neighborhood was selected to represent the high exposure scenario on the basis of the percentage of BLLs $\geq$ 10 µg/dL, rather than a physical or demographic resemblance to any particular neighborhood in California. We believe this percentage is representative of high exposure neighborhoods in California.

The average exposure scenario has a blood lead distribution that could be expected in an urban population exposed to average lead levels and representative of the California population as a whole. For this average exposure scenario, the GM and GSD were taken from the BLL distribution of the unexposed comparison area for the Galena, Kansas, Lead Exposure Study (GM = 3.13 µg/dL, GSD = 1.68). Use the average exposure scenario if the high exposure scenario does not apply. Table 1 shows the GM, GSD, and percentage of children with BLLs $\geq$ 10 µg/dL for each of the exposure scenarios.

Table 1 Summary of Statistics for Tier I Default Baseline Blood Lead Levels

Exposure Scenario	GM (µg/dL)	GSD	% BLLs $\geq$ 10 µg/dL
High	3.69	1.84	5.1
Average	3.13	1.68	1.2

Step 4: Estimate the Probability of Children having Blood Lead Levels ≥ 10 µg/dL due to Facility Emissions

In Step 4, we estimate the probability of children in the MEA having BLLs ≥ 10 µg/dL. This is used with the risk management levels in Chapter III, Section D, to make risk management decisions. Table 2 gives the probability for a range of predicted air concentrations for each exposure scenario.

Table 2 Children with Blood Lead Levels ≥ 10 µg/dL for Various Air Lead Concentrations at Two Exposure Scenarios

Air Lead Concentration in the MEA (30-day average) [µg/m^3]	Percent ≥ 10 µg/dL	
	High Exposure Scenario	Average Exposure Scenario
baseline*	5.1	1.2
0.02	5.4	1.4
0.06	6.1	1.7
0.10	6.8	2.2
0.20	8.9	3.4
0.25	9.8	4.1
0.50	15.9	8.9
0.75	22.4	15.4
1.0	29.1	23.0
1.5	42.5	39.0

* The baseline represents BLLs due to lead in soil, dust, water, food, and background air lead concentrations.

Table 2 was constructed using the baseline BLLs for the two exposure scenarios and the aggregate slope[5]. Because Table 2 uses the baseline BLLs as a starting point, it incorporates background exposures. The risk estimate is based on the air concentrations that would be expected due to the emissions from a specific facility. The source of the baseline BLL distributions are discussed above in Step 3 and the basis for selecting these statistics is discussed in Appendix C.

[5] The aggregate slope relates changes in air lead concentration to changes in blood lead. It is aggregate because it incorporates the lead being inhaled directly from the air and the additional lead in soil, dust, food, and water due to deposition from the air. See Appendix D for a brief discussion of the aggregate slope. "Technical Support Document, Proposed Identification of Inorganic Lead as a Toxic Air Contaminant, Part B Health Assessment" March 1997 (ARB, 1997) provides a discussion of the derivation of the aggregate slope for lead.

The risk manager can use Table 2 or the instructions in Appendix E to find the percent of children with BLLs ≥ 10 µg/dL. A reasonable approximation may be obtained by interpolating between the concentrations shown. However, the instructions in Appendix E will give a more precise estimate without the need to interpolate.

In Figure 3 below, we give an example of how to use Table 2 to find the probability of children having blood lead levels ≥ 10 µg/dL.

Figure 3 Calculating Percent Risk using Tier I Methods

Instructions	Example
1. Using an approved air dispersion model, calculate the average air lead concentration in the MEA surrounding the point of maximum impact (30-day averages).	1. The ISCST3 air dispersion model predicts an average air concentration in the MEA of 0.25 µg/m^3. This is the average for the 1 square kilometer area centered on the highest 30-day average concentration.
2. Determine the appropriate exposure scenario.	2. The MEA includes part of a census tract in which the median age of housing is 1958 and 32 percent of the population has an income less than 1.25 times the poverty level. Therefore, the correct exposure scenario is the high exposure scenario.
3. Look up the corresponding risk (percent probability of BLLs ≥ 10 µg/dL) in Table 2, or use the instructions in Appendix E.	3. The entry in Table 2 for the high exposure scenario and 0.25 µg/m^3 is 9.8 percent.

A modified version of this approach can be used to estimate the risk from operations that emit lead for fewer than 30 days. For these short term operations, the non-inhalation risk is less applicable because the air emissions will have ceased before the resulting non-inhalation exposure reaches its peak. Appendix F provides a table that is constructed using the inhalation-only slope to estimate risk from short term emission increases. To estimate risk from these short term emissions, use the instructions given above and the table in Appendix F or the instructions in Appendix E, and a slope factor of 2.0 µg/dL per µg/m^3. This slope factor was recommended by OEHHA for this purpose and is based on studies of direct inhalation in adults. These studies were reviewed by OEHHA in the health assessment which formed the basis for the identification of lead as a toxic air contaminant.

Step 5: Calculate the Facility Contribution to the Blood Lead Level

In this step, we give instructions for calculating what percentage of the average BLL in the MEA is attributable to the emissions from the facility. The facility's contribution to the average BLL is needed if the calculations show non-cancer risk is over the approvable level, or the significant risk level (see Chapter III for a discussion of risk management levels). This information will be used to determine whether a new or modified source will be required to

prepare a specific findings report as part of the permitting process or an existing source will be required to prepare a Risk Reduction Audit and Plan (RRAP).

We have recommended this step because, in the high exposure scenario, a source could completely eliminate its emissions and still be unable to reduce risk to below the significant risk level. The requirement to reduce risks to below the significant risk level is part of the Air Toxics "Hot Spots" Program. Risk management levels are discussed in Chapter III.

The contribution of the facility emissions is calculated using the GM and GSD for the BLL distribution that includes the facility emissions and the aggregate slope. Table 3 shows the geometric mean (as opposed to Table 2 which shows the percentage of the BLL distribution $\geq$ 10 µg/dL) BLL for each exposure scenario at selected air concentrations above background. It was constructed the same way as Table 2 but gives the geometric mean.

Table 3 Geometric Mean Blood Lead Levels for Various Air Lead Concentrations at Two Exposure Scenarios

Air Lead Concentration in the MEA (30-day average) [µg/m^3]	Geometric Mean BLL (µg/dL)	
	High Exposure Scenario	Average Exposure Scenario
baseline*	3.69	3.13
0.02	3.76	3.20
0.06	3.90	3.35
0.10	4.04	3.50
0.20	4.38	3.86
0.25	4.56	4.05
0.50	5.43	4.97
0.75	6.30	5.88
1.0	7.17	6.80
1.5	8.92	8.64

The calculation of facility contribution to the BLL first involves finding the arithmetic equivalent of the GM in Table 3. Because the geometric mean is a logarithmic function, you cannot add the product of an arithmetic function to it until you convert it to the arithmetic equivalent. The next step is calculating the BLL due to the air lead concentration resulting from the facility's emissions. This is the product of the air lead concentration and the aggregate slope. The last step is dividing the air lead concentration-related blood lead by the arithmetic mean. Figure 4 is an example of how to calculate facility contribution to mean BLLs using Table 3. The facility contribution is the percentage of the mean BLLs due to the air lead from the facility.

Figure 4 Calculating Facility Contribution to Mean Blood Lead Levels

Instructions	Example
1. Find the GM and GSD for the calculation. The GM is given in Table 3 for selected air concentrations. Interpolate for air concentrations between those shown. The GSD for the high exposure scenario is 1.84 and for the average exposure scenario is 1.68.	1. In the example in Figure 1, the geometric mean associated with an air lead level of 0.25 $\mu g/m^3$ is 4.56 µg/dL from Table 3 under the high exposure scenario. The GSD for the high exposure scenario is 1.84.
2. Convert the GM to an arithmetic mean: $\mu_C = \exp [\ln(\mu_G) + 1/2((\ln(\sigma_G))^2)]$ where: $\ln(\mu_G)$ is the natural log of the geometric mean, $\ln(\sigma_G)$ is the natural log of the geometric standard deviation, and, μ_C is the arithmetic mean	2. The geometric mean of 4.56 is converted to an arithmetic mean as follows: $\exp [\ln(4.56) + ½ ((\ln(1.84))^2)]$ $= \exp [1.5173 + 0.1859]$ $= \exp [1.7032]$ $= 5.49$ µg/dL
3. Calculate the contribution to the blood lead due to the air lead using the aggregate slope 4.2 $\mu g/dL/\mu g/m^3$.	3. The blood lead at an air lead concentration of 0.25 is: $0.25\ \mu g/m^3 * 4.2\ \mu g/dL/\mu g/m^3$ $= 1.05$ µg/dL
4. Divide the part contributed by the air lead from the facility by the mean blood lead and convert to a percentage.	4. The facility contribution is: $1.05 / 5.49 = 0.19 * 100 = 19$ percent

Step 6: Determine Actions Required

The actions taken on the basis of the findings of this source assessment process will depend on the purpose of the risk assessment. The risk estimate is used for one of two purposes. Under the district permitting program, the risk is used by the district to determine whether to require a new or modified source to install Toxic Best Available Control Technology (T-BACT) and to determine whether and under what conditions a source can be permitted. Under the Air Toxics Hot Spots Program, the risk assessment is compared to district defined significant risk levels to determine whether the source needs to notify the public of the potential risk, whether they are required to develop a RRAP, and under what time frame the RRAP must be implemented.

If the assessment is being done to support a permit application and the district finds that the risk is above the significant risk level, the source has three options. First, the source could request the district to permit the project based on a specific findings report, second, the source could modify the project to reduce the risk, or third, the source could apply to the district to do the assessment using Tier II or Tier III methods. If the assessment is being done for the Hot Spots program and would trigger any of the requirements, the source may still apply to the local

air district to do the assessment using Tier II or Tier III methods. Chapter III offers recommendations for significant risk levels to be used in permitting and Hot Spots determinations. These recommended levels are for guidance purposes, ultimately the districts determine the risk levels to be used in these evaluations.

2. Tier II - Estimating Neurodevelopmental Risk Using Site-Specific Lead Measurements

In Tier II, the probability of children having BLLs $\geq$ 10 µg/dL is based on site-specific measurements of lead concentrations in soil and dust, the modeled air lead concentrations, and site specific measurements or default values of lead concentrations in food and water. In this section, we give a general outline of the process for doing a Tier II assessment. This approach relies on the use of the IEUBK[6] model. The IEUBK model and the site-specific lead concentrations are used to calculate the percent of children with BLLs $\geq$ 10 µg/dL. The IEUBK model uses lead concentrations in soil, dust, air, food, and water to calculate a range of BLLs and the probability of occurrence of each (a probability distribution) for an individual child exposed to those conditions. The model can be used for a maximum exposure area by constructing a table of exposure parameters to represent each of the homes in the maximum exposure area. One set of parameters may represent more than one home. The table should contain columns for the lead concentrations and the number of children exposed to each set of concentrations. The model can then be used to estimate the risk for each group of children. The community risk is calculated by aggregating the risk for all the children. For detailed instructions on using the IEUBK model, you will need to consult the IEUBK Guidance Manual.

When used with existing lead concentrations, the IEUBK model calculates current risk. It can be used to predict risk due to increased emissions through the use of supplemental equations as described in Step 4 on pages 25 and 26. The OEHHA provided values to be used in the supplemental equations to estimate the increased soil and dust lead levels due to the increased air lead. See Appendix D for a more detailed discussion of the IEUBK model.

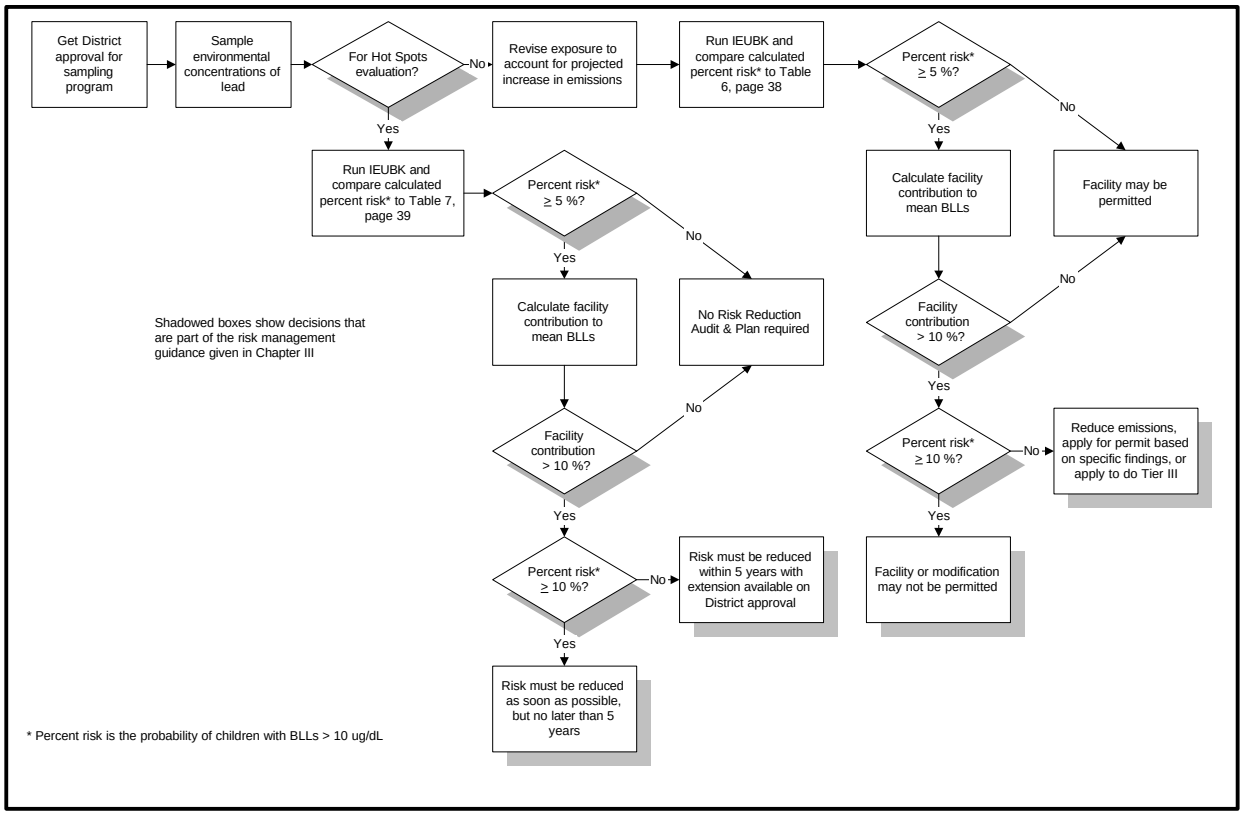
The IEUBK is designed for estimating risk to children. As of the release of this document, the ARB staff has not identified an approvable alternative blood lead model. If there are no residences in the MEA, the source has three options. First, the source may propose to use the IEUBK model to evaluate risk consistent with these guidelines. In this case, the source must propose a soil and dust sampling plan similar to that required when using the model for children. Second, a source may elect to conduct a Tier III analysis. Third, a source may propose the use of an alternative blood model. The district may approve the use of an alternative model with the

[6] The IEUBK model version 0.99 and the Guidance Manual are available for purchase from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA, 22161. Refer to PB 93-963510. The NTIS also takes phone orders at (703) 487-4650 or (800) 553-6847 from 8:30 to 5:30 EST weekdays, by e-mail at order@ntis.fedworld.gov, or by fax at (703) 321-8547.

concurrence of ARB. The ARB will evaluate the use of an alternative approach or model on a site specific basis within 60 days of the date the district requests the evaluation. The ARB will evaluate an alternative approach or model for general use within 180 days of the date the district requests the evaluation.

The use of the IEUBK to calculate the baseline percentage of BLLs ≥ 10 µg/dL will require a sampling plan designed to adequately characterize the exposure to children in the maximum exposure area from all sources of lead in the environment. The air concentration to use in calculating the baseline BLL will depend on whether you are calculating the risk due to a new or an existing source. Assessment of a new source will use the background air lead levels for the baseline while assessment of an existing source will use background plus source-specific air lead concentrations. Once the baseline blood lead distribution is found using the IEUBK, the increased risk from projected increases in emissions can be calculated. Figure 5 is a flowchart of the steps to be followed as part of Tier II.

Figure 5 Detailed Approach Using Tier II Methods



When soil and/or dust will be sampled for lead concentrations in homes to characterize exposure in a maximum exposure area near a facility, the facility will need to contact the local Public Health Officer and the California Department of Health Services Childhood Lead Poisoning Prevention Branch (CLPPB) in advance to inform them of the intent and scope of the sampling. To assist the facility in contacting the CLPPB, a form is provided in Appendix K. The facility should also consult with the local air district on its plans to conduct sampling. The U.S. EPA, the Department of Housing and Urban Development (HUD), and American Standards and Testing Methods (ASTM) all have published guidance on soil and dust sampling for lead concentrations[7]. An individual conducting sampling for lead in soil and dust must be certified by the California Department of Health Services as a Lead Inspector/Assessor and must comply fully with California regulations as set forth in Title 17, California Code of Regulations, Division 1, Chapter 8; Accreditation, Certification, and Work Practices for Lead Based Paint and Lead Hazards.

Step 1: Estimate the 30-Day Air Concentration in the Maximum Exposure Area

The 30-day average is calculated as in Section A Step 1 using an air dispersion model. As in Tier I, use the air concentration in the area in which the maximum predicted air lead concentration occurs. Because the air lead concentration will vary over the area, a graphical depiction of the air concentrations in the affected area will be needed to develop the exposure table.

Step 2: Identify the Exposure Conditions for the Population in the Maximum Exposure Area

The exposed population would be the same as that identified for Step 2 of Section II B. For Tier II, however, additional information about the number of children in the affected area will be used in the exposure table. If there are no residences in the MEA, the source may pro-pose the use of an alternative model. The district could approve the use of an alternative model, with ARB's concurrence.

We expect that air, soil, and dust lead concentrations will vary over the area. Therefore, a graphical depiction of the air lead and a soil and dust sampling plan designed to adequately depict

[7] Guidance available to assist sources in developing a sampling plan include the following: EPA 747/R-95-001, Residential Sampling for Lead: Protocols for Dust and Soil Sampling, Final Report, March 1995; HUD Guidelines for the Evaluation and Control of Lead Based Paint Hazards in Housing, Chapter 7; ASTM E 1727 Standard Practice for Field Collection of Soil Samples for Lead Determination by Atomic Spectrometry Techniques; ASTM E 1728 Standard Practice for Field Collection of Settled Dust Samples Using Wipe Sampling Methods for Lead Determination by Atomic Spectrometry Techniques; and Provisional Standard (PS) 46 Practice for the Collection of Surface Dust by Air Sampling Pump Vacuum Technique for Subsequent Lead Determination.

the exposure potential in the area should be developed. The results of the soil and dust sampling and predicted air concentrations will be entered into an exposure table. Each line in such a table is used in the model to represent exposure to some portion of the children in the maximum exposure area.

An accurate estimate of the dispersion of the BLLs in the maximum exposure area cannot be obtained by using the area average for the air, soil, and dust levels. If site-specific lead levels for food and water can not be obtained, area averages and/or defaults given for the IEUBK by the U.S. EPA can be used.

Step 3: Determine the Existing Percent of Blood Lead Levels ≥ 10 µg/dL Using Site-Specific Data with the Integrated Exposure Uptake Biokinetic Model

Instead of using default BLL distributions as in Tier I, a facility operator can develop a baseline BLL distribution from site-specific estimates of lead concentrations in soil, dust, air, food, and water using the IEUBK model.

The soil and dust sampling should be representative of the levels to which children in the MEA are exposed. Representative sampling can be used for homes with significant similarities. Use the sampling results and the air quality modeling to construct a table that represents the various environmental concentrations to which the children of the community are or would be exposed and show the number of children exposed to each set of concentrations.

Using the IEUBK and the exposure table, calculate the probability of a BLL ≥ 10 µg/dL for each child. The model will give a set of probable BLLs and the probability of each (called a probability density) for each of the sets of environmental conditions in the exposure table. It can be used to calculate a distribution of possible BLLs for a group of children exposed to the same concentrations even if they don't live in the same residence. This distribution of possible blood lead concentrations depicted by the IEUBK model represents the effect of inter-individual variability. This is important because it illustrates the effect of behavior and physiology in predicting blood lead levels. The model uses a GSD of 1.6 to represent the inter-individual variability which is variability not related to differences in the concentrations in soil, dust, air, food, and water. To estimate the risk in the MEA, the model would have to be run for each set of environmental concentrations in the exposure table and the resulting risk for each child aggregated.

For a new source, the air lead concentration used in the IEUBK model to calculate baseline BLLs should be the background air lead concentration for the air basin. For an existing source, the air lead level to be used in the IEUBK model should be the sum of the modeled air lead concentrations from the current source emissions and the background air lead concentrations for the air basin. This is because the air lead concentrations derived in Step 1 are exclusively the lead concentrations due to emissions from the source. If there will be no increase in emissions, as

would be the case for an existing source doing a risk assessment for the Hot Spots program, the baseline risk is compared with the risk management levels. Depending on the level of risk found and the district designated significant risk level, the source might need to complete Step 5.

Step 4: Estimate the Probability of Blood Lead Levels ≥ 10 µg/dL due to New or Increased Emissions

In this step, we discuss the process for estimating risk when emissions are expected to increase as a result of a new source or modifications to an existing source. To estimate the projected percent of BLLs ≥ 10 µg/dL at the increased emission rate from a new or modified source, you can run the IEUBK model with an updated exposure table. Use the background air lead concentrations plus the air lead concentrations estimated for the facility including the projected increase. Calculate the projected increase in the soil lead and dust lead using the supplemental equations. Use the same inputs for food and water as in Step 3. Then run the IEUBK model with the new inputs, and aggregate the result.

The supplemental equations are given below. They were developed for the IEUBK by the U.S. EPA and are discussed in the guidance manual for the IEUBK. The values to be used in the equations are given in Table 4. These values were developed by the OEHHA and are dis-cussed in Section 4 of the Technical Support Document, Proposed Identification of Inorganic Lead as a Toxic Air Contaminant, Part B Health Assessment (ARB, 1997). This document is available on the ARB website at www.arb.ca.gov.

Table 4 Parameters for Use in the Supplemental Equations S1 and S2

Parameter	Column 1 urban mix of sources	Column 2 large point source
a_1	510	206
c_1	844	551

To predict soil lead concentrations when air lead concentrations increase, use Equation S1.

Equation S1: $S = a_0 + a_1 * A$

Where:

S is the increased soil lead concentration to be used in the IEUBK model;

a_0 is the initial site-specific soil lead concentration measured for the IEUBK analysis;

a_1 is taken from Table 4 (column 1 values are for areas with typical urban sources and column 2 are for areas more strongly impacted by a single source); and,

A is the air lead concentration associated with the new facility emissions.

To predict dust lead concentrations when air lead concentrations increase, use Equation S2.

Equation S2: $D = c_0 + c_1 * A$

Where:

D is the increased dust lead concentration to be used in the IEUBK model;

c_0 is the initial site-specific dust lead concentration measured for the IEUBK analysis;

c_1 is taken from Table 4 (column 1 values are for areas with typical urban sources and column 2 for areas more strongly impacted by a single source); and,

A is the air lead concentration associated with the new facility emissions.

Step 5: Calculate the Facility Contribution to the Blood Lead Levels

If you are using the Tier II approach to estimate risk for an existing facility, the simplest way to calculate the contribution of the facility to the geometric mean blood lead levels for the maximum exposure area is to use the aggregate slope as illustrated in Figure 4 on page 20.

Another way to calculate facility contribution is to use the IEUBK model. However, using the IEUBK model to calculate the facility contribution is more complicated. It is more complicated because the measured concentrations in dust and soil already include the contribution from existing air emissions from the facility. To use the IEUBK model, you would have to predict what the soil and dust concentrations would be in the absence of emissions from the facility. This could be done with the supplemental equations. You would then run the IEUBK model again as you did for Step 3, using the background air lead and the predicted soil and dust levels. The difference in means would be the exposure due to the facility's emissions. This would then be divided by the mean calculated in Step 4 and multiplied by 100 to find the percentage of the mean BLL that was due to the facility. The IEUBK has a feature that attributes the risk to the various media. However, the value this feature attributes to air is only the risk due to inhalation and, therefore, is not the equivalent of the instructions in this paragraph and should not be used with the risk manage-ment levels in Chapter III.

Step 6: Determine Actions Required

The actions the source may choose to take on the basis of the results of this assessment will depend on the purpose of the risk assessment. Under the district permitting program, the risk is used by the district to determine whether to require a new or modified source to install toxic Best Available Control Technology and to determine whether and under what conditions a source can be permitted. If the assessment is being done to support a permit application and the risk is found to be significant, the source has three options. One would be to request the district to permit the project on the basis of a specific findings report. Another would be to modify the project to reduce the risk. A third would be to do the risk assessment using Tier III.

Under the Air Toxics Hot Spots Program, the risk assessment is compared to local air district-defined risk levels to determine whether the source needs to notify the public of the potential risk, whether they are required to develop a RRAP, and under what time frame the RRAP must be implemented. If the assessment for Hot Spots indicates the source must take action to notify the public or reduce the risk, the source can request the district to allow them to assess the risk using Tier III. In Chapter III, we make recommendations for risk levels to be used in permitting and Hot Spots determinations. However the district has the statutory authority to set risk levels for these purposes.

3. Tier III - Estimating Neurodevelopmental Risk using Actual Blood Lead Levels

In this section, we describe an approach to calculating neurodevelopmental risk using the results of blood lead testing in the MEA. If a facility operator feels that the Tiers I and II options do not accurately portray the actual BLLs in the maximum exposure area, the operator can request that the district allow blood lead testing to establish site-specific baseline GM BLL and GSD to determine the number of children with BLLs of concern. Because of the complexity and expense associated with this approach, we expect this approach to be rarely used. This option involves the collection of confidential medical information and involves human subjects. Therefore, the facility operator will need to contract with a university or public health agency to carry out the study. The district, the Public Health Officer, and the CLPPB will need to be included in all aspects of the planning and execution of the study. In addition, the district will have to review and approve the study design and the contractor. Figure 6 is a flowchart of the steps to be followed in a Tier III evaluation.

Step 1: Estimate the 30-Day Air Concentration in the Maximum Exposure Area

The 30-day average is calculated as in Section A Step 1 using an air dispersion model. As in Tier I, use the air concentrations in the area in which the maximum offsite air concentration is predicted to occur. For an existing source, the main use of the modeling is to identify the exposed population. For a new source, the concentrations are needed to predict how the existing BLL distribution will be changed. Any change in the emissions or release parameters will require revised air dispersion modeling.

Step 2: Identify the Exposed Population

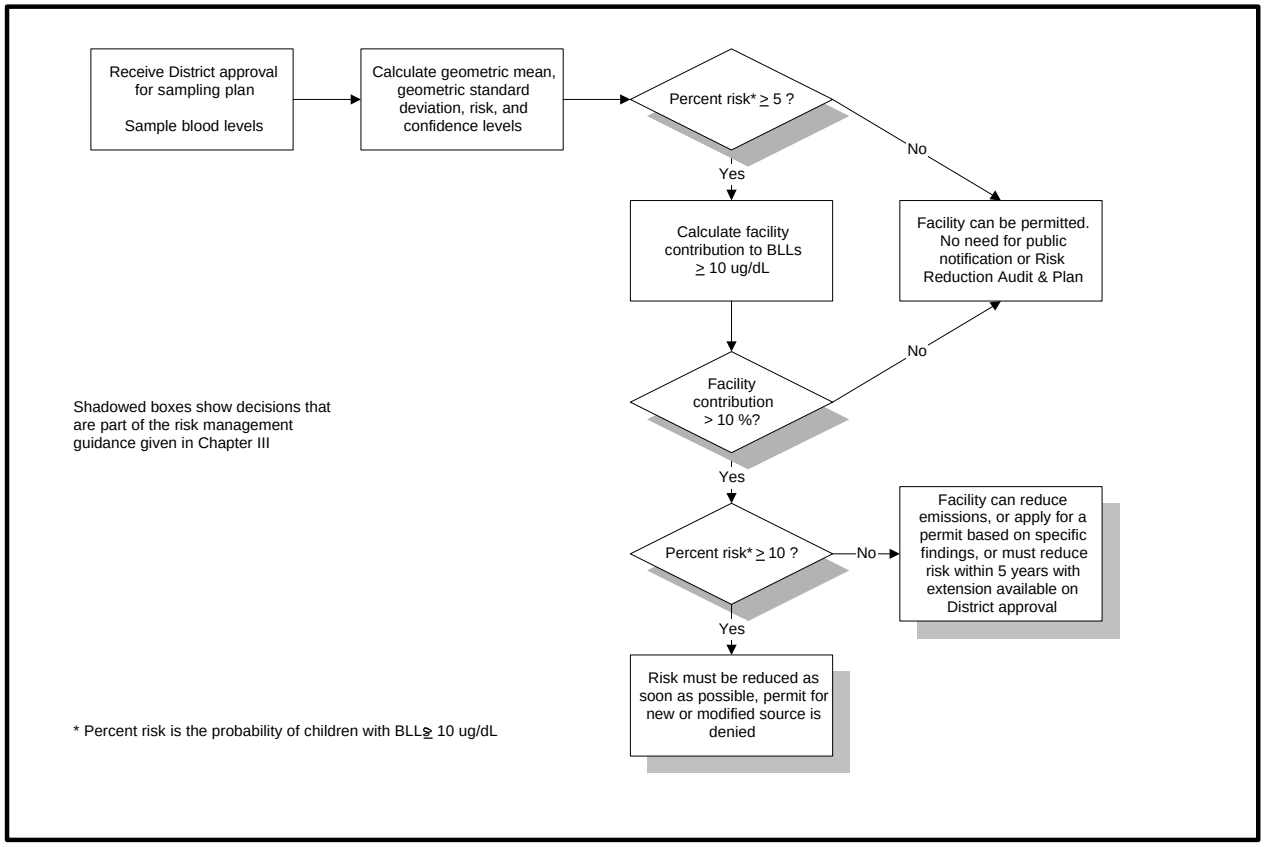
The exposed population would be the same as that identified for Step 2 of Section B.

Step 3: Determine the Baseline Blood Lead Distribution Using Blood Lead Sampling

Blood lead sampling needs to be done in a way that accurately represents the area and is likely to include the most exposed persons. Because the effect of lead exposure may differ by

ethnicity and income, it is important for the sampling plan to ensure that all segments of the exposed population are represented.

Figure 6 Detailed Approach Using Tier III Methods



Determination of the number of children to be sampled is dependent on the characteristics of the distribution, the statistics needed, and the desired levels of precision and accuracy. To eval-uate neurodevelopmental effects, both the GM and the percent of children with BLLs ≥ 10 µg/dL are characterized by determining the sample size for each statistic and using the greater of the two.

Appendix G contains a discussion of how precision and accuracy relate to the number of children to be sampled. Appendix G also contains tables and related formulae for determining the number of children that would need to be tested to achieve a desired level of precision and accuracy. These data are provided to assist the district in evaluating any proposed blood lead sampling plans. Appendix G contains tables for a large population and equations that can be used to relate those tables to smaller populations. We are not recommending that a specific precision and accuracy be required. However, we are recommending that the precision and accuracy attained in a given study be documented in the report to the district and be reported to the public, if public

notification is triggered. Failure to find children with BLLs of concern in a given blood sampling program does not necessarily mean that there is no risk. It may reflect poor precision or accuracy, the effect of chance, or sampling bias.

Step 4: Estimate the Probability of Blood Lead Levels ≥ 10 µg/dL due to Facility Emissions

From the sampling data, calculate a GM and GSD. The GM and GSD are used as shown in Appendix E to calculate the probability of BLLs ≥ 10 µg/dL. The process involves calculating the Z-score, and finding the associated percentage on a table of Z-scores. The percentage found on the table of Z-scores is subtracted from 1 if the mean is less than 10 µg/dL.

For a facility using Tier III to characterize risk from an existing facility for compliance with the Hot Spots Program, the calculated probability of BLLs ≥ 10 µg/dL will be the facility risk. For a facility seeking a permit to modify or a new facility, it will be the baseline risk and the increased risk due to the projected increase in emissions will need to be calculated and added to the baseline.

The site-specific baseline blood lead distribution calculated in Step 3 forms the baseline for a facility seeking a permit to modify an existing facility or construct a new facility. The additional risk due to increased emissions can be calculated by applying the blood lead/air lead slope calcu-lated for children (4.2 µg/dL blood lead per $\mu g/m^3$ air lead). Because the slope is a linear function, you must first convert the geometric mean to an arithmetic value to add the product of the slope and increased air lead. Appendix E gives the instructions for making this calculation. Using these instructions, you can calculate the change in the geometric mean blood lead and additional per-centage risk of children having a blood lead level ≥ 10 µg/dL as a result of the projected increase in emissions.

Step 5: Calculate the Facility Contribution to the Blood Lead Levels

The calculation of facility contribution would be done as shown in Figure 4 (Tier I, Step 5) using the aggregate slope.

Step 6: Determine Actions Required

Sources that have done Tier II and Tier III analyses, have fewer options. The available options will depend on the purpose of the risk assessment. Under the district permitting program, the risk is used by the district to determine whether to require a new or modified source to install T-BACT and to determine whether and under what conditions a source can be permitted. If a risk assessment is done to support a permit and finds the source will result in significant risks, the source has two remaining options. One would be to request the district to permit the source on the basis of specific findings. The other would be to change the proposed project to reduce the risk. Under the Air Toxics Hot Spots Program, the risk assessment is compared to district defined risk levels to

determine whether the source needs to notify the public of the potential risk, whether they are required to develop a RRAP, and under what time frame the RRAP must be implemented. If an assessment for the Hot Spots Program shows an action is required and all the Tiers have been used, the only option left is to comply. In Chapter III, we make recommendations for risk levels to be used in permitting and Hot Spots determinations. However, the district has the authority to designate the risk levels for use in permitting and Hot Spots.

C. Cancer Effects Analysis

In this section, we briefly discuss procedures for cancer risk analysis. The cancer risk analysis produces an estimate of the maximum offsite cancer risk or the maximum individual cancer risk whichever the district requires. Cancer risk from all carcinogens emitted are summed to estimate the facility cancer risk. For further information, see the OEHHA Risk Assessment Guidelines, Part II (OEHHA, 1999).

Step 1: Estimate the Maximum Annual Average Ambient Concentration

Use an approved atmospheric dispersion model with facility-specific emission rate and release parameters to estimate the maximum annual average offsite air concentration at an existing receptor as directed by the district. See the CAPCOA Risk Assessment Guidelines for modeling instructions.

Depending on whether a source is a new source or an existing source seeking a permit to modify, and the levels of risk found, a source may need to evaluate the risk before and after application of control technology, and the project and overall source risk. Any change in the emissions or release parameters will require revised air dispersion modeling.

Step 2: Estimate the Inhalation and Non-Inhalation Cancer Risk

To estimate inhalation cancer risk, multiply the unit risk factor by the maximum annual average air concentration calculated in Step 1. The unit risk factor recommended by the OEHHA for lead is 1.2×10^{-5} per $\mu g/m^3$. For some substances, including lead, the inhalation risk is only a part of the risk. Additional risk from the emissions to the air occur when airborne lead gets in or on household surfaces, water, and food. The contribution of these secondary routes of exposure are evaluated by using a dispersion modeling post-processing model such as the ARB Health Risk Assessment (HRA) model to calculate non-inhalation risk. The HRA model can be down-loaded from the ARB web site, www.arb.ca.gov. For an order form to purchase the HRA users manual with an electronic version of the HRA model, contact the ARB Emission Assessment Branch office at (916) 323-4327.

The inhalation and non-inhalation risks are added together to derive the cancer risk from lead. This is then added to the risk from all other potential carcinogens emitted from the source to derive the total cancer risk due to the source.

Step 3: Determine Actions Required

If a detailed risk assessment is done according to the risk assessment guidelines, the only options available are to modify the project or comply. The district determines whether to require a new or modified source to install T-BACT and whether and under what conditions a source can be permitted. Under the Air Toxics Hot Spots Program, the district defines risk levels to determine whether the source needs to notify the public of the potential risk, whether they are required to develop a RRAP, and under what time frame the RRAP must be implemented. In Chapter III, we make recommendations for risk levels to be used in permitting and Hot Spots determinations.

III. Risk Management Guidelines

This Chapter presents the staff's suggested approach for evaluating new, modified, and existing lead emission sources. In this Chapter, we discuss applicability, define key terms, discuss the approach for permitting new and modified sources, and summarize additional requirements. The suggested approach frequently presents only one method for handling each element of the proposal. We acknowledge that alternative approaches may be acceptable for a particular district.

The districts have permitting authority for stationary sources and are also responsible for setting public notification and risk reduction levels for the Hot Spots Program. The districts evaluate applications for permits to construct new sources or to modify existing sources. In this evaluation, the district considers the effect of the proposed changes on the overall air quality in its jurisdiction and the potential effect on public health. In reviewing applications for permits to construct new or modified sources, the district must decide whether the new or modified source can be permitted and when to require the source to install Toxic Best Available Control Technology (T-BACT). We have designed these guidelines to be consistent with the Risk Management Guidelines for New and Modified Sources of Toxic Air Contaminants (ARB, 1993).

With regard to existing sources that are evaluated under the Hot Spots Program, districts must set the risk levels at which public notification and risk reduction audits and plans are required, and determine the timing of the required risk reductions.

We examined a number of data sources to guide our risk management recommendations and selection of default values for assessment procedures. We evaluated several strategies and reviewed numerous blood lead studies. We also looked at levels used by other agencies and for similar types of chemicals or similar types of health effects. These considerations and studies are discussed in detail in Appendices C and H.

A. Applicability

These guidelines are intended to apply to any new, modified, or existing stationary source that is required to obtain a permit or comply with the Hot Spots Program pursuant to district regulations.

B. Key Terms

In this section, we define key terms used in this Chapter.

Facility Contribution

The facility contribution is the percentage of the average (geometric mean) BLL in the maximum exposure area which is a result of the lead emissions from the facility.

Maximum Excess Cancer Risk (MECR)

The maximum excess cancer risk (MECR) is an estimate of the highest increased cancer risk resulting from a project's or source's emissions of carcinogens including lead. The MECR is the maximum individual offsite cancer risk. See the OEHHA Risk Assessment Guidelines, Part IV (OEHHA, 2000) for details.

Maximum Exposure Area

The area within 1 square kilometer of the maximum offsite concentration.

Maximum Offsite Concentration

The highest air concentration predicted by the air dispersion model at an offsite location or at an offsite receptor depending on district requirements. The district could allow the use of monitoring data if that data were of sufficient quality.

Modification

A modification is either:

(1) the addition of any new permit unit at an existing source; or
(2) any physical change in, change in method of operation of, or addition to an existing permit unit that requires an application for a permit to construct and/or operate. Routine maintenance and/or repair shall not be considered a physical change. A change in the method of operation of equipment, unless previously limited by an enforceable permit condition, shall not include:

a) an increase in the production rate, unless such increases will cause the maximum design capacity to be exceeded; or
b) an increase in the hours of operation; or
c) a change in ownership of a source.

Permit Unit

A permit unit is any article, machine, piece of equipment, or other contrivance, or combination thereof which may cause or control the release of lead and which requires a written permit.

Project

A project is any permit unit or grouping of permit units or other activities which emit lead, located on one or more contiguous properties within a district, including properties that are separated solely by a public road or other public right-of-way, and are owned or operated by the same person (or by persons under common control).

Specific Findings Report

Specific findings are made by the district when permitting a source that imposes a risk above specified levels. The source may submit data to support the district's findings. The specific findings are made public in a report containing the reasons that support the decision to grant or deny a permit.

Stationary Source or Source

For the purposes of these Guidelines, a stationary source or source refers to all permit units or activities which emit lead located on one or more contiguous properties within a district, including properties that are separated solely by a public road or other public right-of-way, and are owned or operated by the same person (or by persons under common control).

Toxic Best Available Control Technology (T-BACT)

T-BACT means the most effective emissions limitation or control technique which:

(1) has been achieved in practice for such permit unit category or class of source; or
(2) is any other emissions limitation or control technique, which includes process and equipment changes of basic and control equipment, found by the Executive Officer or Air Pollution Control Officer to be technologically feasible for such class or category of sources, or for a specific source.

Although the definition of T-BACT does not explicitly state that cost is considered when determining T-BACT, in practice we recognize that T-BACT decisions implicitly take cost into consideration.

C. Definition of Risk Management Levels

In the permitting process, the districts make decisions about the need for control technology and whether new sources or modifications to existing sources can be permitted. For this purpose, the district identifies the following risk levels:

1) a T-BACT trigger level. This is the risk level at which the district would require a source to install T-BACT on the new source or the new equipment at an existing source;
2) an approvable level. Below this level, the district could approve a new source or modification to an existing source without a Specific Findings Report; and
3) a permit denial level. At a risk equal to or above this level, the district would deny a permit.

The district may require existing sources which are subject to the Hot Spots Program to do a risk assessment. Depending on the results of that risk assessment, the source may have to notify the public of the risk assessment results and may be required to reduce the risk. The districts are required to define the following risk management levels for the Hot Spots Program:

1) a notification level. This is the risk level at which facilities need to notify the exposed population (this could be the same as the significant risk level);
2) a significant risk level. At this level, facilities would be required to implement a risk reduction audit and plan. The risk reduction audit and plan must show how the facility will reduce the risks to below this level; and
3) an unreasonable risk level. Facilities with risks equal to or above this level must reduce their risks within five years or less.

D. Risk Management Levels for the Simplified Approach for Assessing Non-Cancer Risks

In this section, we present a simplified risk management approach for use by districts and sources in determining non-cancer risks. It is based on the simplified approach presented in Chapter II, Section A. For permitting new and modified sources, we provide recommendations for a T-BACT trigger level, an approvable level, and a permit denial level. For the Hot Spots Program, we make recommendations for public notification, significant risk, and unreasonable risk levels, shown in Table 5. In Appendix H, we discuss the basis for these recommended risk management levels. As explained in Chapter II, this approach would not apply to sources where the maximum exposure area had a high potential for existing exposure. Children in these areas need a greater level of protection because of the high background exposure potential.

Table 5 Recommended Risk Management Levels Using the Simplified Approach (Chapter II. A.) for Assessing Non-Cancer Risks

Lead Permitting Levels		**Hot Spots Program Levels**	
T-BACT trigger level	Emissions $\geq$ 1 pound per month	Notification level[1]	Maximum offsite air concentration $\geq$ 0.30 $\mu g/m^3$
Approvable level[1]	Maximum offsite air concentration $\leq$ 0.30 $\mu g/m^3$	Significant risk level[1]	Maximum offsite air concentration $\geq$ 0.30 $\mu g/m^3$
Permit denial level[1]	Maximum offsite air concentration $\geq$ 0.55 $\mu g/m^3$	Unreasonable risk level[1]	Maximum offsite air concentration $\geq$ 0.55 $\mu g/m^3$

[1] *Not applicable to high exposure areas.*

We are recommending T-BACT be required for any new source that will emit more than 1 pound of lead per month and any existing source where a modification will result in an increase in emissions of 1 pound per month. This recommendation is based on consideration of current ambient lead levels and both cancer and non-cancer risk. At this emission level, we estimate that neurodevelopmental risks would not be increased by more than 1 percent and cancer risk would be less than 1 in a million.

At an air concentration greater than or equal (≥) to an approvable level, but below the permit denial level, a source could be permitted on the basis of a specific findings report. For the simplified approach, we are recommending an air concentration from the facility of less than or equal to (≤) 0.30 μg/m^3 as the approvable level. We are recommending a permit denial level for the simplified approach at ≥ 0.55 μg/m^3. At 0.30 μg/m^3, we estimate there will be less than a 5 percent probability of BLLs exceeding 10 μg/dL in children who do not live in a high exposure area. At 0.55 μg/m^3, we estimate there will be no more than a 10 percent probability of BLLs exceeding 10 μg/dL except in a high exposure area. These air concentrations are the 30-day average maximum offsite air concentrations due to the emissions from the facility. These air lead concentrations were chosen by examining the data and evidence detailed in Appendix H and selecting levels that did not represent an unacceptable public health risk.

In the Hot Spots Program, for the simplified approach we recommend the public notification level and the significant risk level both be set at an air concentration of 0.30 μg/m^3 and the unreasonable risk level be set at 0.55 μg/m^3.

E. Risk Management Levels for Permitting New and Modified Sources Using the Detailed Approaches (Chapter II. B.)

In this section, we present our recommendations of levels for districts to use in permitting new and modified sources. In developing these recommendations, we considered two types of information. We considered the regulatory precedents set by other agencies and for other pollutants. We also considered the risks to communities from all sources of lead exposure. See Appendix H for a discussion of the basis and rationale for these risk management recommendations.

1. Level of Emission Control Required

For non-cancer or cancer effects of lead, these Guidelines recommend levels that would trigger the requirement for further control. For lead, we are recommending a T-BACT trigger based on an emission rate rather than risk levels. We have chosen this approach in recognition of the data needs and complexity of the risk assessment process.

We are recommending T-BACT be required for any new source that will emit more than 1 pound of lead per month and any existing sources where a modification will result in an increase of emissions of 1 pound per month. This recommendation is based on consideration of current ambient lead levels and both non-cancer and cancer risk. At this emission level, we estimate that neurodevelopmental risks would not be increased by more than 1 percent and cancer risk would

be less than 1 in a million. This is consistent with the ARB Risk Management Guidelines (ARB, 1993) and the Department of Toxic Substances Control's (DTSC) "point of departure"[1] for risk management.

2. Risk Following Application of Control

The requirement for T-BACT is based on new or increased emissions (i.e, the project risk.) while the permitting decisions are based on the source risk. If T-BACT is required, the non-cancer or cancer health risks following application of T-BACT to the project must be recalculated using the reduced emissions. This is the risk due to the facility as a whole. If the project is a new facility, the project risk is the same as the source risk.

3. Consideration of Source Risk

The following is a description of the way the recommended levels would be applied for districts that adopt the recommended levels listed in Table 6. If the source risk for all potential health effects is below the approvable level as defined by the district, the district my permit the facility. If the source risk is above the denial level as defined by the district, the district will not issue the permit. If the source risk is above the approvable level and below the denial level for neurodevelopmental risk, and the percent contribution of the facility is below the significant level, the district may grant the permit. Otherwise, the district may grant the permit on the basis of a specific findings report. See Appendix I for details on how to prepare a Specific Findings Report. See Table 6 for the recommended approvable levels for new and modified sources.

Table 6 Recommended Permitting Levels for New and Modified Sources

	Neurodevelopmental Effects	**Cancer**
T-BACT trigger level	emissions ≥ 1 pound per month.	emissions ≥ 1 pound per month.
Approvable level	overall source risk: 5% probability of children ages 0-7 years with BLLs ≥ 10 µg/dL or facility percent contribution to BLLs is ≤ 10% (when the probability is > 5% but < 10%).	maximum excess risk due to emissions from the facility < 10/million among all residents and workers (district may permit sources between 10 and 100 per million based on specific findings)
Permit denial level	overall source risk: ≥10% probability of children ages 0-7 years with BLLs ≥ 10 µg/dL	maximum excess risk due to emissions from the facility ≥ 100/million among all residents and workers

[1] DTSC's "point of departure" is generally regarded as a level below which no action need be taken. At levels above this, the agency may consider other factors such as land use, technical feasibility, or cost in determining appropriate risk management actions.

For the detailed risk management approach, we are recommending a 5 percent or less probability of BLLs ≥ 10 µg/dL for neurodevelopmental risk and 10 in a million cancer risk as the permit approvable levels. These are consistent with the U. S. EPA's definition of "poses a risk" (U.S. EPA, 1998) and the ARB Risk Management Guidelines (1993).

For the permit denial level, we are recommending the districts use a 10 percent probability of BLLs ≥ 10 µg/dL for neurodevelopmental risk and 100 in a million for cancer risk. This is based on a consideration of achievable emission rates and is consistent with the CDC recommendations and the ARB's Risk Management Guidelines. An analysis of the potential impacts of these recommended levels is found in Section F.

4. Consideration of Facility Contribution for Modification to Existing Sources - Neurodevelopmental Effects

If the facility contribution is less than the approvable level, the district may approve the permit. If the facility contribution is over the approvable level but the overall source risk is less than the denial level, the district may issue a permit based on specific findings. If the overall source risk is greater than or equal to the denial level, the permit is denied. See the neurodevelopmental effects column of Table 6 for the recommended levels. We recommend a facility contribution of 10 percent in consideration of the other sources of exposure.

F. Risk Management Levels for Existing Sources Using the Detailed Approaches (Chapter II. B.)

Table 7 shows the recommended levels for existing sources complying with the Hot Spots Program. We based these recommendations on an evaluation of risk for a number of existing sources and on risk management decisions made by other regulatory agencies.

Table 7 Hot Spots Program Levels for Existing Sources

	Neurodevelopmental Effects	**Cancer**
Notification level	overall source risk ≥ 5% probability of children ages 0-7 years with BLLs ≥ 10 µg/dL or percent facility contribution > 10% (when the probability is > 5% but < 10%).	maximum excess risk due to emissions from the facility ≥ 10/million among all residents and workers
Significant risk level	overall source risk ≥ 5% probability of children ages 0-7 years with BLLs ≥ 10 µg/dL or percent facility contribution > 10% (when the probability is > 5% but < 10%).	maximum excess risk due to emissions from the facility ≥ 10/million among all residents and workers
Unreasonable risk level	overall source risk ≥ 10% probability of children ages 0-7 years with BLLs ≥ 10 µg/dL	maximum excess risk due to emissions from the facility ≥ 100/million among all residents and workers

G. Impact of the Recommended Levels

In this section, we examine some of the potential effects of these recommended risk management levels. In Table 8, we present the estimated air concentrations that would be associated with the proposed neurodevelopmental risk management levels for the two exposure scenarios in the Tier I analysis. The concentrations shown in Table 8 were calculated from the risk management levels. To evaluate where a specific source would fit, a person would need to know the source emissions and do the appropriate air dispersion modeling.

Table 8 Air Concentrations Associated with Proposed Neurodevelopmental Risk Management Levels

	High Exposure Scenario	**Average Exposure Scenario**
Approvable level	< 0.12 μg/m^3 (based on $\geq$ 10 percent contribution to the mean BLL)	< 0.30 μg/m^3
Approvable level with specific findings required	≥ 0.12 μg/m^3 and < 0.26 μg/m^3	≥ 0.30 μg/m^3 and < 0.55 μg/m^3
Permit denial level	≥ 0.26 μg/m^3	≥ 0.55 μg/m^3
Public notification	≥ 0.12 μg/m^3 (based on $\geq$ 10 percent contribution to the mean BLL)	≥ 0.30 μg/m^3
Significant risk level	≥ 0.12 μg/m^3 (based on $\geq$ 10 percent contribution to the mean BLL)	≥ 0.30 μg/m^3
Unreasonable risk level	≥ 0.26 μg/m^3	≥ 0.55 μg/m^3

As Table 8 shows, any facility with a percent contribution greater than 10 percent must make public notification. People who are aware of the high level of risk may be able to take action to reduce the exposure. A Specific Findings Report would be required for any new facility or modification to an existing facility in a high exposure area if we did not consider the percent contribution. Our initial assessment of the census tracts in Los Angeles County indicates about 17 percent of the census tracts would qualify as high exposure areas.
will not drive any risk management decisions but would be a contributing risk for sources that emit other carcinogens.

Table 9 shows the air concentrations that would be associated with the proposed levels for cancer risk.

There is an apparent contradiction in allowing a new facility to be permitted at an air concentration that would trigger a risk reduction audit and plan for an existing source. However, permitting decisions are typically based on the maximum operating capacity of the facility and Hot Spots Program assessments are based on actual emissions which are typically less than the maximum capacity.

Table 9 Lead Air Concentrations Associated with Cancer Risk Management Levels.

Risk Management Levels	Lead Concentration (inhalation only)
Approvable level	$< 0.84\ \mu g/m^3$
Approvable level - specific findings required	$\geq 0.84\ \mu g/m^3$ but $< 8.4\ \mu g/m^3$
Permit denial level	$\geq 8.4\ \mu g/m^3$
Public notification	$\geq 0.84\ \mu g/m^3$
Significant risk level - Risk must be reduced to the designated significant level within 5 to 10 years	$> 0.84\ \mu g/m^3$
Unreasonable level risk - risk must be reduced within 5 years or less	$\geq 8.4\ \mu g/m^3$

H. Additional Requirements

Health and Safety Code (H&SC) section 42301.6 (a) states that prior to approving a source application for a permit to construct or modify, the Air Pollution Control Officer (APCO) must determine if the source is within 1000 feet from the boundary of a school site. If the source is located within 1000 feet of the school site, the APCO must prepare a public notification describing the proposed project or modification. At the expense of the permit applicant, the APCO must distribute or mail the notice to the parents or guardians of children enrolled in any school within one-quarter mile of the of the source and to each address within 1,000 feet of the source (H&SC section 42301.6(b)). The notices must be sent at least 30 days prior to the date the APCO takes final action.

Note that the school in H&SC section 42301.6(b) is not necessarily the same as the school site in HS&C section 42301.6(a). H&SC section 42301.9 defines "school" as "any public or private school used for purposes of the education of more than 12 children in kindergarten or any of grades 1 to 12 inclusive, but does not include any private school in which education is primarily conducted in private homes." "School site" is not defined, but legislative history indicates that school site refers to property acquired for past or future school construction (Statutes 1991, Chapter 1183). If the source is within 1,000 feet of the outer boundary of a school site, notification is required. Neither a school building nor enrolled children are necessary for this requirement to apply.

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Appendix A

Environmental Lead and Exposure Trends

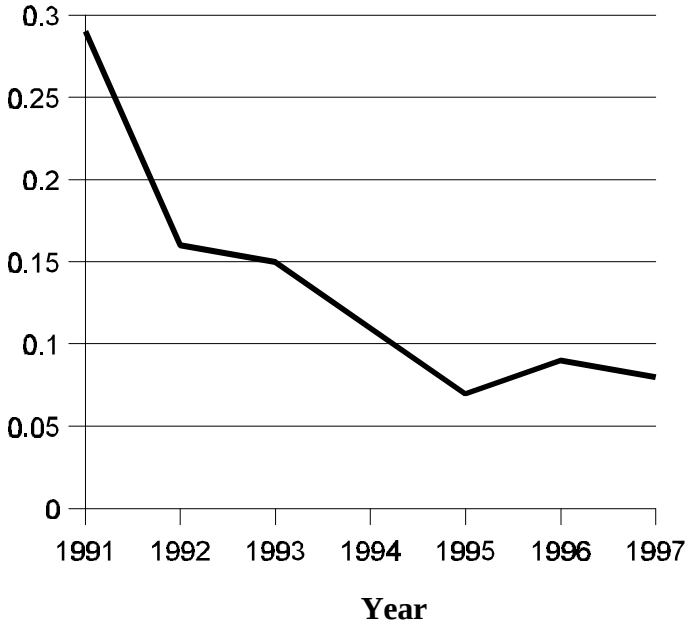
Appendix A

Environmental Lead and Exposure Trends

Environmental Lead Trends

Over the past several years, exposure to lead from environmental media (food, water, and air) has declined, and average blood lead levels in the population have declined as well. Today, at most air monitoring sites in California, concentrations of lead in the ambient air are far less than the State Ambient Air Quality Standard of 1.5 µg/m^3 over a 30-day averaging time. At criteria pollutant monitoring network sites (State/Local Air Monitoring Stations (SLAMS) or National Air Monitoring Stations (NAMS) which are intended to represent population exposure), the highest monthly means have dropped from 0.29 µg/m^3 in 1991 to 0.08 µg/m^3 in 1997. Figure A-1 shows the monthly mean lead concentration at the highest criteria pollutant monitoring site in the State from 1991 to 1997. The site with the highest monthly mean would not necessarily be the same site from year to year.

Figure A-1: Statewide Maximum Monthly Mean Lead Concentrations



Another way to characterize the ambient concentration decreases is to look at the number of times per year that the monthly mean exceeded 0.10 µg/m^3 at SLAMS/NAMS stations. This is summarized in Table A-1.

Table A-1
Number of Site-Months with Lead Concentrations[1] ≥ 0.10 µg/m^3

Year	Number at or over 0.10 µg/m^3
1991	19
1992	7
1993	3
1994	3
1995	0
1996	0
1997	0

[1] at SLAMS/NAMS sites

Some special purpose monitors located near large sources or locations potentially affected by historic emissions have detected higher concentrations. Monthly mean concen-trations up to 1.83 µg/m^3 at one site in 1993 and 3.98 µg/m^3 at another in 1994 have been measured. These values are believed to be the result of unusual events or conditions.

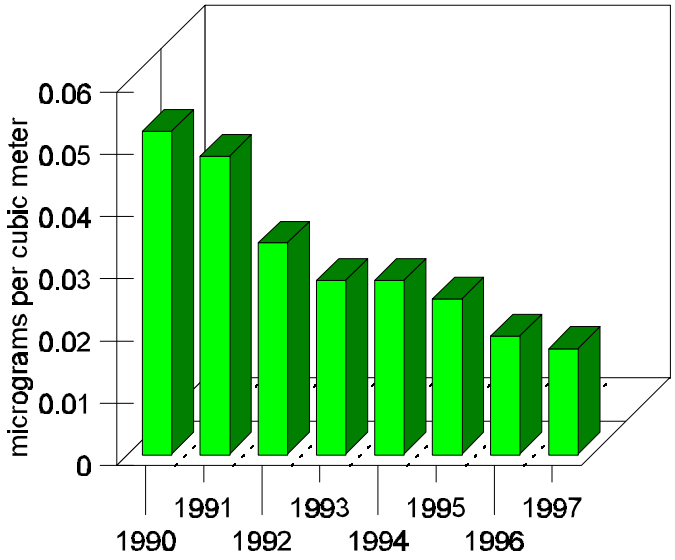
The statewide population-weighted annual mean concentrations of lead in the ambient air have dropped precipitously over the last 20 years. Figure A-2 shows the reduction in the statewide population-weighted annual mean air lead concentrations for the years 1990 to 1997.

Annual mean lead levels higher than the surrounding urban background concentrations of 0.01 to 0.03 µg/m^3 have been measured in industrial areas which are near large lead processing facilities and major freeways. These higher than average levels have occurred despite the current use of highly effective lead emission controls on the facilities. The sources and district continue to monitor and address the cause(s) of the air lead levels above background.

Blood Lead Level Trends

The U. S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC) has investigated the distribution of blood lead levels (BLLs) in the United States population using large cross-sectional national surveys. These studies have shown decreasing BLLs over the last two decades.

Figure A-2: Statewide Population-Weighted Annual Mean Lead Levels



The second National Health and Nutritional Examination Survey (NHANES) II was conducted from 1976 to 1980. The population was surveyed again from 1988 to 1991 for NHANES III, phase 1 and from 1991 to 1994 for phase 2. These large-scale studies have documented an overall decrease in blood lead levels of 78 percent for persons aged 1 to 74 years between NHANES II and NHANES III, phase 1. In the NHANES II study, an estimated 88.2 percent of one to five year old children in the United States had blood lead levels greater than or equal to (≥) 10 µg/dL. In phase 1 of the NHANES III survey, 8.9 percent of 1 to 5 year old children were determined to have blood lead levels ≥ 10 µg/dL. Table A-2 illustrates the changes in the blood lead distributions between phases 1 and 2 of the NHANES III survey for children 1 to 2 years old and for children up to age 7.

Table A-2
Comparison of Results from NHANES III Phases 1 and 2

	Phase 1	Phase 2	Phase 1	Phase 2
Children aged 1- 2 yrs	**Nationwide**		**Western Region**	
Total sampled	924	987	308	218
Geometric mean BLL, µg/dL	4.05	3.14	3.39	2.40
Geometric standard deviation, µg/dL	2.06	2.09	1.96	2.03
# with blood leads over 10 µg/dL (%)	123 (13)	67 (7)	24 (8)	6 (3)
# with blood leads over 15 µg/dL (%)	46 (5)	22 (2)	6 (2)	1 (0)
Children aged 0 - 7 yrs				
Total sampled	2,506	2,619	891	585
Geometric mean BLL, µg/dL	3.31	2.7	2.49	2.18
Geometric standard deviation, µg/dL	2.15	2.09	2.08	1.94
# with blood leads over 10 µg/dL (%)	271 (11)	160 (6)	49 (5)	13 (2)
# with blood leads over 15 µg/dL (%)	87 (3)	51 (2)	9 (1)	2 (0)

Appendix B

Census State Data Centers and Instructions For Retrieving Data

Appendix B

Census State Data Centers

In this Appendix, we list the designated Census State Data Centers for the U.S. Census. These are organizations that can help districts and permit applicants obtain data from the census files.

Census State Data Centers: California

Census State Data Center-Department of Finance
915 L Street
Sacramento, CA 95814
Ms. Linda Gage, Director
(916) 322-4651
Mr. Richard Lovelady
(916) 323-4086
FAX (916) 327-0222
filgage@dof.ca.gov
http://www.dof.ca.gov/html/Demograp/internet/druhpar.htm

Sacramento Area COG
3000 S Street, Suite 300
Sacramento, CA 95816
Kelly Grieve
(916) 457-2264
FAX (916) 457-3299
kgrieve@sacog.org
http://www.sacog.org

Association of Bay Area Governments
Metro Center
8th and Oak Streets
P.O. Box 2050
Oakland, CA 94604-2050
(510) 464-7937
FAX (510) 464-7970
http://www.abag.ca.gov

Southern California Association of Governments
818 West 7th Street, 12th Floor
Los Angeles, CA 90017
Mr. Javier Minjares
(213) 236-1800
minjares@scag.ca.gov

San Diego Association of Governments
Wells Fargo
401 B Street, Suite 800
San Diego, CA 92101
Ms. Karen Lamphere
(619) 595-5300
kla@polaris.sandag.cog.ca.us

State Data Center Program
University of California-Berkeley
2538 Channing Way #5100
Berkeley, CA 94720-5100
Ms. Ilona Einowski/Fred Gey
(510) 642-6571
archive@ucdata.berkeley.edu

Association of Monterey Bay Area Governments
445 Reservation Road, Suite G
P.O. Box 809
Marina, CA 939-0809
Christy Oosterhous
Mr. Jim Werle
(408) 883-3750
ambag@mbay.net

Instructions for Retrieving Census Data on the Internet

The census access is set up to retrieve summary statistics on several levels, such as State, County, census tract, zip code. The following instructions give step-by-step guidance for obtaining the data needed to determine the appropriate exposure scenario for a Tier I assessment of neurodevelopmental risk.

In your web browser, go to http://homer.ssd.census.gov/cdrom/lookup.

Before you can obtain information for the affected census tract(s), you must have done the air dispersion modeling to identify the location of the maximum off-site air concentration and determined which census tract(s) are within ½ kilometer of that location. One can purchase the data to be used with GIS Software to graph the location of the census tract boundaries or consult the state data centers

To obtain the data for the census tract(s), go to the census website at http://homer.ssd.census.gov/cdrom/lookup, choose STF3A to open the next page. There, select California and mark "go to Level State--County (*Tracts and Block Groups)" and click on submit. At this page, select the county in which the facility is located or the county in which the affected neighborhood is located if different than the facility location and mark "go to level State--County--Census Tract (*Block Groups)." When you click on submit, this will bring up a listing of census tracts from which you can select the tract or tracts in which the maximum exposure area is located. Select the census tract(s), mark "retrieve the areas you've selected below," click submit, choose "Tables to retrieve" and click submit again. On the list of Tables that comes up, select P121 ratio of income in 1989 to poverty level, universe:persons for whom poverty status is determined and H25A Median year structure built, universe: housing units. When you click submit, you will be asked to specify the format for the data. HTML is easy to read and will give you something like the following:

Database: C90STF3A
Summary Level: State--County--Census Tract

Tract 1043: FIPS.STATE = 06, FIPS.COUNTY90 = 037, FIPS.TRACT90 = 1043

RATIO OF INCOME IN 1989 TO POVERTY LEVEL
Universe: Persons for whom poverty status is determined
under .50.....867
.50 to .74.....816
.75 to 0.99.....246
1.00 to 1.24.....801
1.25 to 1.49.....635
1.50 to 1.74.....267
1.75 to 1.84.....598
1.85 to 1.99.....486
2.00 and over.....3775
MEDIAN YEAR STRUCTURE BUILT
Universe: Housing units
Median year structure built.....1958

To calculate the percentage of the persons with an income less than 1.25 times the poverty level, you would sum the numbers of persons in the first 4 categories, divide by the sum of the

people in all the categories, and multiply by 100. In this example, the sum of the first 4 categories is 2730 and the sum of all the categories is 8491. 2730/8491 = 0.322 or 32 percent. This census tract has both a median age of housing older than 1960 and more than 30 percent of the population with an income less than 1.25 times the poverty level so this is a high exposure area.

Appendix C

Baseline Blood Lead Levels and Exposure Scenarios

Appendix C

Baseline Blood Lead Levels and Exposure Scenarios For the Tier I Analysis

Selecting a Geometric Mean and Geometric Standard Deviation to Represent the High and Average Exposure Scenarios

Increased exposure to lead will increase the blood lead of exposed persons. The Office of Environmental Health Hazard Assessment (OEHHA) has found that there is no evidence of a threshold for neurodevelopmental effects and has provided a slope factor relating the air lead to the blood lead levels (BLLs). In terms of the significance of blood lead concentration for an individual, the U.S. Department of Health and Human Services' Centers for Disease Control and Prevention (CDC) has identified a BLL in children of 10 µg/dL as a level of concern and has recommended that regulatory efforts should be directed to minimizing the number of children with BLLs at or over this level. (CDC, 1991)

Because lead from multiple sources can impact the BLLs of children, an evaluation of the effect of a given level of air lead emissions on BLLs in a population of children requires knowledge about the distribution of baseline BLLs. These reflect the contribution of other sources and body burdens due to previous exposure to all sources. There will be a range of BLLs in any population that will reflect the various sources of exposure plus behavioral (e.g. mouthing behavior) and physiological factors such as nutritional status.

What are the geometric mean and the geometric standard deviation and why are they important?

BLLs have been found to be log-normally distributed; that is, the BLLs do not fit the normal distribution but the natural logarithms of the BLLs do. Therefore, when the values are transformed to their log equivalents, the statistical tools developed for the normal distribution can be used with them. Thus, the geometric mean (GM) and geometric standard deviation (GSD) can be used to find the percentage of the distribution above a specific value in the same way that the mean and standard deviation are used with a normal distribution. The GM and GSD describe the shape of the curve and can be used to calculate the percent of the population (or probability of an individual in the population) having a BLL of 10 µg/dL or more.

We are using BLLs of 10 µg/dL in these Guidelines as the primary benchmark for decision-making consistent with CDC's recommendation that regulatory efforts be directed at minimizing the number of children with BLLs at or over this level.

The GM describes the midpoint of the distribution while the GSD describes the spread of the distribution. In two distributions with the same GM, the one with the larger GSD will have a greater percentage of values $\geq$10 µg/dL. The spread of the distribution of BLLs reflects the variability for a given population.

There are two sources of variability: the environmental variability and the inter-individual variability. The environmental variability stems from the variability in the soil, dust, air, water, food, and other sources of exposure. The inter-individual variability can be calculated by grouping all the children of the same age exposed to the same environmental concentrations and calculating a GSD for each group. This technique can be used to generate a site-specific inter-individual GSD. A site specific inter-individual GSD takes into account factors such as the bioavailability of the lead in the soil and dust. It describes the effect of the behavioral and physiological factors mentioned above for a specific location. The United States Environmental Protection Agency (U.S. EPA) has recommended the use of an inter-individual GSD of 1.6 for estimating risk using the Integrated Uptake Exposure Biokinetic (IEUBK) Model for Lead in Children. The IEUBK is a model used to predict BLLs when the environmental concentrations are known.

How does geometric mean and geometric standard deviation relate to estimating risk?

We have proposed that neurodevelopmental risk from lead be defined as the probability of children in the Maximum Exposure Area (MEA) having BLLs $\geq$ 10 µg/dL. We arrived at this recommendation after evaluating several other ways of evaluating risk.

We have proposed three tiers of analysis for estimating risk. Tier I is a generic approach that requires minimal site-specific information on concentrations of lead in environmental media other than air. Tier II relies on site-specific measurements of lead in dust and soil and the IEUBK Model to generate predicted BLLs. Tier III involves actual blood lead sampling to define the baseline BLLs.

As testing to determine every person's blood lead level may be impractical, the Tier I analysis offers a reasonable alternative. However, providing this approach requires that we identify baseline BLLs. We evaluated three approaches to defining baseline BLLs for the Tier I option. The first approach is to use a GM and GSD based on evaluating data gathered over a large geographic region, referred to as a regional approach. The second approach is based on using the inter-individual GSD to calculate risk to the individual living at the location with the highest air concentration caused by the emissions from the facility, known as the maximum individual risk. The third approach is to calculate risk to the population living within a certain geographical distance of the location with the highest air concentration caused by the facility. This is characterized as the neighborhood approach.

The regional approach

The best data available on BLLs in the United States was developed by the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, in the third National Health and Nutrition Examination Survey (NHANES III). The NHANES III data give a GM and GSD that is representative of the population of the U.S. and certain

subgroups (i.e. the people of the western region). These data are based on representative sampling of thousands of people across the country. Data from this survey are referred to as regional data because it is gathered over a large geographical area. As such, it is problematical for evaluating facility impact because it may incorporate greater variability in environmental concentrations than would be likely in a smaller area impacted by emissions from a single facility. It is likely that there is a greater variation in environmental concentrations regionally than would be seen in a community or neighborhood.

The maximum individual approach

In calculating risk from a single facility, we can look at the increased risk to the individual exposed to the highest concentration (maximum individual risk) or to the population in general. Cancer risk is characterized in both of these ways. The calculation of maximum individual risk requires a different approach to defining baseline BLL than a population-based approach. For the maximum individual risk approach, the appropriate GSD would be the inter-individual GSD when the concentrations in air, water, soil, and dust are known. Population risk can be expressed two ways. One, as the number of children in the population expected to have BLLs $\geq$10 µg/dL or two, as the individual average probability of any child in the population having a BLL $\geq$10 µg/dL.

When the environmental concentrations are not known, as in a Tier I analysis, one must either choose a larger GSD or choose a baseline blood lead concentration to account for high environmental concentrations and sensitive populations. The use of the mean of a distribution such as NHANES for a baseline blood lead concentration would not be health protective because at the mean, half of the children would have higher baseline BLLs. We could choose to use the BLL that represents some other percentage of the distribution, such as the 90^{th} , 95^{th} , or 99^{th} percentile blood lead. However, those choices could be too restrictive given that they would incorporate the assumption that all sources of elevated blood leads are at the high end of the range at the locations being evaluated. These concerns led us to consider a third approach.

The neighborhood approach

The neighborhood approach looks at the average individual risk for a child in the maximum exposure area resulting from the facility emissions. To evaluate the feasibility of this approach, staff sought studies of BLLs in communities to evaluate whether there was any difference in GSD between regional, community, or neighborhood populations and to identify appropriate BLL statistics for each exposure scenario. The results of this analysis are given below.

What BLL studies were evaluated?

Published reports of 20 environmental health studies in which lead exposure was a concern were carefully evaluated. They are listed in Table C-1 and full citations are given at the

Table C-1 Twenty Environmental Health Studies

1. Palmerton Lead Exposure Study
2. Multisite Lead and Cadmium Exposure Study with Biological Markers Incorporated
3. Biological Indicators of Exposure to Lead RSR Smelter Site in Dallas, Texas
4. The Third National Health and Nutrition Examination Survey (NHANES III)
5. Bingham Creek Environmental Health Lead and Arsenic Exposure Study
6. Leadville / Lake County Environmental Health Lead Study
7. Midvale Community Lead Study
8. Lead and Cadmium Exposure Study, Galena, Kansas
9. Evaluation of the Risk from Lead and Arsenic, Sandy, Utah
10. The Butte- Silver Bow County Environmental Health Lead Study
11.The Impact of a Los Angeles County Stationary Lead Source on the Blood Lead Levels of Children Living Nearby
12. Missouri Respiratory Study: Forest City and Glover, Missouri
13.Cherokee County Kansas Lead Surveillance Program
14. The Relationship of Human Levels of Lead and Cadmium to the Consumption of Fish Caught In and Around Lake Coeur D'Alene, Idaho
15. A Cohort Study of Current and Previous Residents of the Silver Valley; Assessment of Lead Exposure and Health Outcomes
16. McClellan Air Force Base Cross-Sectional Health Study, Sacramento
17. Ottawa County Blood Lead Testing Project
18. Health Study of Communities Surrounding OTIS Air National Guard Base/Camp Edwards Falmouth, Massachusetts
19. Study of Disease and Symptom Prevalence in Residents of Yukon and Cokesburg, Pennsylvania
20. Lead and Mercury Exposure Screening of Children in Pompton Lakes

end of this Appendix. Most of these studies examined BLLs or other indices of exposure in small towns or cities with known stationary sources of lead exposure. Many of these sources no longer operate and some have been closed for 60 years or more.

In the first 11 of these studies, the researchers made systematic measurements of blood lead levels in children less than 7 years of age. In the other 9, the researchers either did not take representative samples, did not include children, or used another index of exposure. In 10 of the first 11 studies, the researchers measured BLLs in neighborhoods or communities. The NHANES III data, by contrast, were gathered for selected Census Blocks throughout the country

and not specifically for source impacted populations. In 3 of the 10 studies, the community was segmented into smaller areas. In 4 studies, neighborhoods were selected to represent certain exposure conditions. In the other 3, either multiple communities or a whole community were sampled. The 3 studies in which the neighborhoods are segments of the community were useful for researching the question of whether the GSD for a community is necessarily larger than the GSD for a neighborhood as has been suggested. For the purposes of this analysis, we defined a neighborhood as an area less than 3 squared kilometers (km^2) and a community as an area of more than 3 km^2 and less than 200 km^2. However, as we will show later in this Appendix, we found that community BLLs did not differ from neighborhood BLLs when the number of children sampled was greater than 50.

The spread in a set of measurements, such as BLLs, is described in the GSD. The spread of the data represents the variability in the BLLs and reflects a number of factors. Among them are the environmental concentrations and behavioral factors that result in ingestion of soil and dust, physiological and chemical factors that affect absorption of inhaled or ingested lead, previous exposure, and measurement variability. To use the GM and GSD from one population to predict the percent of BLLs $\geq$ 10 µg/dL in another population, one must have reasonable confidence that there is enough similarity in the two populations with regard to the factors affecting the variability and exposure.

Commenters on previous drafts of this document have said that the greatest variability would be seen in regional BLL studies and that the use of the regional data would overstate the risk for an individual or neighborhood impacted by a specific facility. In regional BLL studies, GSDs ranged from 1.92 to 1.99 in 4 subsets from the Multisite Lead and Cadmium Study which collected data from communities in four states. In the NHANES survey, the GSD for white children in the Western Region was 1.74, the GSD for black children was 2.08, and the GSD for all children in the Western Region was 1.94.

Community studies showed GSDs ranging from 1.51 to 2.12, with the median at 1.68. These community GSDs were not universally lower that the GSDs from the regional studies. The distribution of GSDs for the regional studies was congruent with the upper quartile of the community studies and of the neighborhood studies. To evaluate which studies should be considered in defining the baseline BLLs, we also examined the GSDs for communities as compared to neighborhoods. Tables C-2 and C-3 show the GSDs for the communities and neighborhoods, respectively.

Overall, neighborhood GSDs ranged from 1.13 to 2.07 with the median at 1.62 as compared to the community studies with a range from 1.51 to 2.12 with a median at 1.68. Within individual studies we can see that the neighborhood GSDs ranged fairly widely around the community GSD. Table C-4 gives statistics for the 3 studies in which the community was divided into smaller areas (Leadville, Bingham Creek, and Palmerton) and for Butte where selected neighborhoods were sampled. The median of the neighborhood GSDs were lower than

Table C-2 Community Geometric Standard Deviations

Study Location (Data Set Used)	GSD
Dallas, Texas (area 3)	1.51
Los Angeles (gradient graphical treatment for values above 5)	1.55
Los Angeles (analytic method for values above 5)	1.55
Bingham Creek, Utah (all)	1.56
Dallas, Texas (areas 1-4)	1.66
Dallas, Texas (area 2)	1.66
Palmerton, Pennsylvania (all)	1.67
Galena, Kansas (unexposed comparison)	1.68
Dallas, Texas (areas 1-5)	1.68
Dallas Texas (area 5, unexposed comparison)	1.76
Leadville, Colorado (all)	1.77
Butte, Montana (all)	1.81
Galena, Kansas (exposed)	2.12
Los Angeles (complete data set)	unavailable

the community or cumulative GSDs. However, neighborhood GSDs are not necessarily lower than community GSDs.

As can be seen in Table C-3, the data show a clear association between small sample size and lower GSDs. If we only look at neighborhoods in which the sample size exceeds 50, we see the range of GSDs is much smaller (from 1.45 to 2.07) with the median at 1.63. This range is very similar to the range for community GSDs. If we look at the neighborhoods with a sample size less than 50, we see the range is from 1.13 to 2.16 with a median at 1.57. This does not appear to be a function of area size because the GSDs for the neighborhoods with areas less than 0.5 km^2 have GSDs ranging from 1.5 to 1.83. The data indicate that neighborhood GSDs are not generally lower than community GSDs when sample sizes are over 50. Therefore, we are excluding those neighborhoods or communities with sample sizes less than 50 to avoid shortcomings associated with small samples.

Table C-3 Neighborhood Geometric Standard Deviations

Number sampled > 50		
Study Location (Data Set Used)	**GSD**	**N**
Bingham Creek (area G)	1.45	99
Bingham Creek (area A)	1.48	96
Bingham Creek (area C)	1.49	118
Dallas (area 4)	1.51	70
Bingham Creek (area D)	1.52	187
Bingham Creek (area F)	1.6	156
Bingham Creek (area B)	1.62	117
Bingham Creek (area E)	1.63	60
Sandy	1.63	105
Midvale (all)	1.66	181
Leadville (area C)	1.72	91
Leadville (area D)	1.76	72
Midvale (random)	1.77	112
Butte (area A)	1.84	183
Bingham Creek (area H)	2.00	56
Dallas (area 1)	2.07	53

Number sampled < 50		
Study Location (Data Set Used)	**GSD**	**N**
Bingham Creek (area J)	1.13	4
Palmerton (area I)	1.15	3
Leadville (area H)	1.29	19
Palmerton (area B)	1.37	2

Number sampled < 50		
Study Location (Data Set Used)	**GSD**	**N**
Bingham Creek (area K)	1.41	43
Palmerton (area F)	1.45	13
Palmerton (area K)	1.45	16
Leadville (area B)	1.47	21
Butte (area E)	1.5	27
Butte (area F)	1.52	17
Palmerton (area E)	1.54	19
Leadville (area F)	1.55	20
Leadville (area G)	1.55	39
Palmerton (area C)	1.57	19
Butte (area G)	1.62	13
Palmerton (area G)	1.63	19
Palmerton (area J)	1.66	9
Butte (area B)	1.67	15
Bingham Creek (area I)	1.7	33
Leadville (area M)	1.72	11
Palmerton (area A)	1.72	8
Butte (area D)	1.79	11
Palmerton (area D)	1.8	20
Leadville (area E)	1.83	11
Butte (area C)	1.89	12
Palmerton (area H)	1.92	12
Leadville (Area A)	2.16	31

Table C-4 Comparison of Community Geometric Standard Deviation to Neighborhood Geometric Standard Deviation

Study	Community GSD	Range of Neighborhood GSDs	Median of Neighborhood GSDs
Palmerton	1.67	1.15 - 2.07	1.57
Bingham Creek	1.56	1.13 - 2.00	1.52
Leadville	1.77	1.47 - 2.16	1.72
Butte	1.81	1.50 - 1.89	1.73

How will the GMs and GSDs be used?

Because there are some neighborhoods where high numbers of older housing and low incomes can result in high baseline BLLs, we are proposing that the Tier I screening approach include two exposure scenarios. Thus, we need to select GMs and GSDs to represent the high baseline BLLs, and the average baseline BLLs. This approach protects populations with a high potential for exposure due to other sources without imposing excessive requirements on facilities that are not so located.

Ideally, the GMs and GSDs should be chosen from studies that have environmental characteristics similar to the areas they are being used to represent. However, we do not have adequate data to make a choice on that basis. The factors that have been most consistently associated with elevated BLLs are low income and lead in paint, soil, and dust. Additional factors that moderate the association with lead in soil and dust are accessability of the soil and the contribution to the dust of soil and paint. Only 2 of the studies were conducted in areas with climatic conditions similar to most of California and in areas potentially affected by sources similar to those with the highest known emissions in California.

In the study of Hacienda Heights BLLs (Los Angeles County), dust lead concentrations were generally low with less than 1 percent of the samples greater than 400 ppm. There were also fewer than 1 percent of the children with BLLs $\geq$ 10µg/dL. This is less than half of the two percent found in NHANES III Phase 2 to be representative of the population of the children in the Western region. Therefore, it is reasonable to conclude that Hacienda Heights is not representative of a high exposure scenario despite the presence of a large lead smelter in the area. In Dallas Area A (the high air exposure area), many of the homes had the contaminated soil removed and replaced. This remediation may make the Dallas Area A lead data set unrepresentative of a typical high exposure scenario.

Since none of the studies are representative of the high exposure scenario on the basis of physical and demographic characteristics, we considered choosing a set of statistics based on the level of risk indicated by the BLLs. We calculated the percentage of children with BLLs $\geq$ 10µg/dL for

each data set. Then we determined what risk level would be representative of each exposure scenario. The U.S. EPA considers 5 percent the upper bound of the probability that would be considered to "pose a threat". Two neighborhoods have statistics that would fit this criteria for a high exposure area; Area C in Leadville (GM = 4.12 µg/dL and GSD = 1.72), and Area A in Butte (GM = 3.69 µg/dL and GSD = 1.84). Soil and dust lead levels in these areas are higher than would be expected in California. However, because there is some question of lower bioavailability and lower probability of exposure in these areas, we propose to use one of these statistical sets for the high exposure scenario even though the environmental concentrations may not be representative of California.

One would expect a higher GSD in an area impacted by a variety of sources. Two examples that illustrate this are areas F and H in Leadville. The GMs in these 2 areas, 6.64 µg/dL and 6.92 µg/dL respectively, are among the highest in Leadville clearly indicating high exposure while the GSDs, 1.55 and 1.29 respectively, are among the lowest. Both are areas in which no exposure due to lead in paint would be expected because both are mobile home parks.

In consideration of all the above and the expectation that high exposure areas in California will be impacted by a variety of source types, we propose that a GM of 3.69 µg/dL and a GSD of 1.84 be used to characterize the high exposure scenario. This yields a probability of having a BLL $\geq$ 10µg/dL of 5 percent.

For the average exposure scenario, we propose the use of statistics from the studies that would result in a probability of 2 percent. The two areas closest to that target level were the low air dispersion area of Dallas, Texas with a GM of 4.56 µg/dL, a GSD of 1.51, and a probability of 2.87 percent; and the comparison area for Galena, Kansas with a GM of 3.13 µg/dL, a GSD of 1.68, and a probability of 1.25 percent. Both of these areas have relatively low dust and soil lead levels. However, the mean BLL for Dallas, Texas is much higher than would be expected in an average population as seen in the NHANES III study. Therefore, we have chosen the statistics from the Galena, Kansas comparison area to represent the baseline blood lead distribution for the average exposure scenario.

Table C-5 shows the statistics we have chosen to use in the Tier I approach to estimating neurodevelopment risk.

Criteria for Selecting the Appropriate Exposure Scenario for a Tier I Screening Analysis

The probability of a child having a BLL $\geq$ 10µg/dL is dependent upon a number of factors, such as exposure to lead in dust, soil, food, water, and air. In a Tier I situation, we will not know the environmental lead concentrations. The air dispersion modeling only gives the additional air exposure and the aggregate model incorporates the secondary exposure in soil and dust due to the modeled air emissions. It neither completely characterizes the concentrations in

Table C-5 Default Statistics for Tier I Neurodevelopmental Risk Estimation

	GM (µg/dL)	GSD
High Exposure	3.69	1.84
Average Exposure	3.13	1.68

the air nor in the soil and dust due to other influences (other sources, paint, historical deposition) on these environmental concentrations. In addition, BLLs are influenced by body burden of lead due to previous exposure, behavioral and physiological factors, the bioavailability of the lead and anomalous sources which can not be known in the context of a screening analysis.

Some known factors have been shown in numerous studies to be associated with higher blood lead levels. One is lead in paint, another is socio-economic status. What is needed for a generic approach is a simple set of criteria using data that are easily obtained and verified.

Therefore for the Tier I analysis, we recommend using age of housing and income as the criteria for choosing an appropriate exposure scenario. Lead in paint has been found to be related to age of housing in a nationwide survey by the Department of Housing and Urban Development (HUD). Table C-6 below illustrates that relationship and is excerpted from a table based on that survey that was presented in "Screening Children for Lead and Managing Childhood Lead Poisoning in California - Recommendations to the California Department of Health Services and Technical Report from the Science and Policy Advisory Panel to the CDHS Childhood Lead Poisoning Prevention Branch (CLPPB), January 1997." As you can see from the data in Table C-6, homes built before 1960 have a much greater probability of having high lead levels in paint than homes built between 1960 and 1979.

Table C-6 Percentage of Occupied U.S. Homes with Lead-Based Paint by Lead Concentration and Year Constructed

Construction Year	Percentage of homes (%) with specified paint lead concentrations			
	≥ 0.7 (mg/cm^2)	≥ 1.0 (mg/cm^2)	≥ 1.2 (mg/cm^2)	≥ 2.0 (mg/cm^2)
1960-1979	80	62	47	18
1940-1959	87	80	74	52
before 1940	94	90	79	75
all homes before 1979	86	74	63	43

The CDHS surveyed homes in 3 urban areas in California. This survey found that overall 71 percent of homes built before 1950 had exterior paint lead levels ≥5,000 ppm compared to 16 percent of post-1950 homes. Thirty-one percent of homes built before 1950 had interior paint lead levels ≥ 5,000 ppm compared to 7 percent of post-1950 homes. Therefore, the likelihood of elevated lead levels will be greater in neighborhoods with a preponderance of homes built before 1950. Since virtually no lead paint is likely to be found in homes built after 1980, the risk from lead in paint is likely to be lower in neighborhoods where most (or all) of the homes were built after 1980.

Based on the findings of these two surveys, it appears that houses built before 1950 pose greater potential to contribute to high baseline blood lead levels than those built between 1950 and 1980. According to the 1990 census data, the median age of housing statewide is 1967 and the associated fraction of housing built before 1950 is 20 percent. A sampling of individual census tracts indicated a median of 1960 is associated with up to 30 percent of housing built before 1950.

Low socioeconomic status is also associated with higher overall lead levels. Income is only one aspect of socio-economic status but has an impact on nutritional status (which affects lead adsorption in the body) and on the likelihood that lead paint will be either in poor condition or removed by someone other than a certified lead paint abatement contractor.

We considered 4 approaches for setting the income criteria. One was a percentage of families with incomes below a specific amount. Another was comparison of the median income for the census tract to a specific amount. A third was relating the median income to the median income for the County. A fourth was the percentage of the population with incomes below the poverty level. Using an index value of a set dollar amount would require periodic review and adjustment to account for inflation. In addition, use of a single value statewide would result in an inequity between counties where the cost of living differed significantly. A relative measurement based on income would not take into account family size which has a large impact on the amount of money available for food and home maintenance. Therefore, we propose that a census tract be designated as high risk if the percentage of the population with incomes less than 1.25 times the poverty level was 30 percent or more and the median age of housing is 1960 or earlier.

The selection of a ratio of income to poverty level of 1.25 was based on the limitations of the reasonably available census data which uses categories in which the nearest break is at 1.25 times the poverty level. The choice of a 30 percent proportion was based on this consideration and research using the NHANES data (Pirkle, 1998). In this analysis, the researchers looked at mean BLLs and how they were related to selected demographic characteristics. Among those demographic characteristics was income. Dr Pirkle found that among children 1-5 years old the incidence of blood leads ≥ 10 µg/dl was 8.0 percent in children in the low income category compared to 1.9 percent for the middle income group and 1.0 for the high income group. Dr Pirkle used a poverty to income ratio of 1.3 times the poverty level to define ‘low income’. Using this data we estimated that if about half of the children were at a poverty to income ratio of 1.3, the percentage of BLLs ≥ 10 µg/dl would be about 5 percent. The BLLs could range from

5 to 8 percent in census tracts with a 50 percent or greater proportion of low income children. Given that the closest income to poverty ratio we could easily obtain from the census data was 1.25 percent and that a higher proportion of children than of adults are poor, we selected a 30 percent proportion as a criteria to identify high exposure areas. Based on the 1990 census data, this designation would apply to 273 of the 1637 census tracts in Los Angeles County.

The U.S. Census Bureau provides a good source of data on income and age of housing for each census tract on its website at http://venus.census.gov/cdrom/lookup. In the census data tables, age of housing is given in 2 ways; as number of housing units built within 1 of 8 ranges of year built, or as the median for the census tract. The ratio of income to poverty level is given as the number of persons in each of 8 categories. From this data you would have to calculate the percentage of persons with incomes less than the poverty ratio as shown in Appendix B.

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Appendix D

Models to Predict Blood Lead Levels

Appendix D

Models to Predict Blood Lead Levels

Models to Predict Blood Lead Levels

Lead in the air contributes to exposure through other pathways because airborne lead can contaminate soil, dust, water, and food. Therefore, characterization of direct inhalation alone is not sufficient.

The following models have been developed specifically to predict blood lead through multimedia pathways. In this Appendix, we discuss the aggregate model, and two disaggregate models, referred to as the Integrated Exposure Uptake Biokinetic (IEUBK) model and the Lead-Spread model. This Appendix describes each model and its applicability.

A. *Aggregate model*

An aggregate model is a reasonably simple way to develop an air lead/blood lead relationship (slope), because it does not require pathway-specific information. It is based on the comparison of two populations exposed to two different air lead concentrations, or the same population at two different air lead concentrations. It accounts for both direct inhalation and secondary routes of exposure. The aggregate approach does not attempt to quantify separately the contribution of airborne lead to soil, water, dust, and food. This model incorporates both the direct and indirect contribution of air concentrations to blood lead levels (BLL) without calculating each component individually. These slopes are used to calculate the increased BLL due to increases in air lead concentration due to emissions from a new or existing source increase, they can not be used to calculate baseline BLLs.

The Office of Environmental Health Hazard Assessment (OEHHA) has used the aggregate model to calculate blood lead/air lead slopes for adults and for children. The OEHHA recommends the use of a slope of 1.8 µg/dL per µg/m^3 of airborne lead for adults and 4.2 µg/dL per µg/m^3 for children (ARB, 1997). These blood lead/air lead slopes are used to calculate the change in BLLs due to a change in the airborne lead concentrations. They can be used with the baseline blood lead distributions from this guidance, or site-specific blood lead studies, to predict a change in blood lead and related effects that would result from a change in air lead concentrations. We have also recommended the use of 2.0 µg/dL per µg/m^3 in limited circumstances to represent inhalation only exposure for children. The number is derived from inhalation studies of adults. It was not recommended in the identification process because the need for this value was not recognized until the identification process was complete.

*B. Disaggregate model*s

A disaggregate model uses a multivariate approach to predict blood lead concentrations. In this approach, the contribution of each variable is estimated separately. This requires separate variables for each component of the non-inhalation exposure. The errors and uncertainties in each component of the disaggregate approach will reduce the precision of an estimate derived from a disaggregate model. This approach is recommended only when there is adequate information on exposure through each pathway (soil, dust, food, and water). This kind of model can be used to calculate a baseline blood lead level. We recommend such an approach as a "Tier II" analysis, to determine neurodevelopmental and/or cardiovascular effects when the facility believes that an analysis based on actual soil and dust lead levels will result in a more accurate estimate of risk. An example of a Tier II disaggregate model is the IEUBK.

1. The IEUBK model

The United States Environmental Protection Agency (U.S. EPA) developed the IEUBK model for lead in children to predict blood lead on the basis of lead concentrations in air, soil, dust, water, and food. We recommend in this guidance that this model be used in the "Tier II" analysis to calculate BLLs of children to age 7.

The inputs for this model can be concentrations in the child's environment, or default values derived from studies deemed applicable by the model's developers. The model allows the user to make rapid calculations of an extremely complex set of equations describing exposure, uptake, and biokinetic functions. It was initially designed to evaluate blood lead distributions in potential soil clean-up actions. It can also be used to predict the impacts on blood lead distributions from various exposure scenarios and assist in evaluating remediation strategies for lead in the human environment. The IEUBK model predicts the likely geometric mean and, assuming an inter-individual geometric standard deviation (GSD) of 1.6, produces a distribution of BLLs that may occur in a child or children given the exposure to lead at 1 residence. The geometric mean of that distribution represents the most likely BLL for the child. The model can also be used to generate a probability of exceeding a BLL of concern. It is applicable only to children up to age 7. Where distinct subgroups have different environmental exposures, the overall risk can be calculated by running the model for each subgroup and using the model to aggregate the results. The aggregate distribution will have a larger GSD because of the range of environmental concentrations.

The ability of these models to predict the blood lead of an individual is limited and will produce a probability distribution rather than a single number. This distribution is described mathematically with a mean and a GSD. The GSD defines the spread of the probabilities which represents the variability. For an individual, this variability reflects individual differences in absorption, excretion, behavioral traits affecting ingestion and inhalation, and measurement error. For a population, the GSD characterizes both the individual variability and the variability in the

concentrations to which the members are exposed. The blood lead distributions generated by the IEUBK model using an inter-individual GSD of 1.6 are based on empirical data on the variability of blood lead levels in children exposed to similar concentrations of lead. In exceptional cases, the GSD can be altered in the model to fit assumptions about the underlying variability. However, the guidance manual for the IEUBK model cautions against changing the default GSD. The manual states that, "The GSD value reflects child behavior and biokinetic variability. Unless there are great differences in child behavior and lead biokinetics among different sites, the GSD values should be similar for all sites, and site-specific GSD values should not be needed."

Appendix E

Calculations for Changes in the Geometric Mean

Appendix E

Calculations for Changes in the Geometric Mean

Calculations of the change in the geometric mean blood lead levels (BLLs) and the probability of BLLs ≥ 10 µg/dL, and the effect of a given level of lead in the air and are illustrated in this Appendix. These calculations were used to create Tables 1 and 2 in Chapter II and Table F-1 in Appendix F. They are used to estimate neurodevelopmental risk. In this Appendix, we provide an example of how to calculate changes in geometric mean (GM). The example calculations start with the baseline for the high exposure scenario, a GM of 3.69 µg/dL, and a geometric standard deviation (GSD) of 1.84. The baseline incorporates the background air lead so the air lead concentrations to be used to calculate the increased BLLs are the air lead concentrations attributable to the emissions from the facility being evaluated. To estimate the increased risk from an increase in the air lead concentrations, the GM is converted to an arithmetic mean to reflect the increase in BLL. The GSD is assumed to remain constant.

1. The geometric mean of 3.69 µg/dL and GSD of 1.84 are to an arithmetic mean. The following equation (equation 1) is used:

   $\mu_C = \exp [\ln(\mu_G) + ½*((\ln(\sigma_G))^2)]$ [Equation 1]

   where: $\ln(\mu_G) = \ln(3.69) = 1.306$, and $\ln(\sigma_G) = \ln(1.84) = 0.610$
   then: $\mu_C = \exp [1.306 + ½*(0.610)^2] = 4.45$

2. To calculate the arithmetic mean at an increased concentration, add the expected increase in air lead concentration (eg. 0.12 µg/m^3) is multiplied by the blood lead/air lead slope of 4.2. This value is added to the calculated arithmetic mean then converted back to the GM.

   = 4.45 + (0.12 * 4.2)
   = 4.95

3. To get the GM at an air lead concentration of 0.12 µg/m^3, put calculated new arithmetic mean into equation 1 and solve for μ_G.

   $\mu_C = \exp [\ln(\mu_G) + ½*((\ln(\sigma_G))^2)]$
   $4.95 = \exp [\ln(\mu_G) + ½*(0.610^{\ 2})]$
   $4.95 = \exp [\ln(\mu_G) + 0.186]$
   $\ln(4.95) = \ln(\mu_G) + 0.186$
   $1.60 = \ln(\mu_G) + 0.186$
   $\ln(\mu_G) = 1.414$
   $\mu_G = 4.11$

4. Next, we can calculate a standardized normal deviate or Z-score, which will determine the percent of the distribution above a given level.

   $Z = (\ln(10) - \ln(\mu_{Gi}))/\ln(\sigma_G)$ [Equation 2]
   $Z = (\ln(10) - \ln(4.11))/\ln(1.84)$
   $Z = 1.46$

   Using a normal table, a Z-score of 1.46 is associated with 7.21 percent. That is, based on the normal distribution, we standardize, and estimate that 7.21 percent of the population will be above 10 given a GM of 4.11 µg/dL and a GSD of 1.84.

5. Calculate arithmetic means for increases in air lead concentrations of 0.05, 0.10, 0.15, 0.20, 0.25, 0.5, and 1.0 $\mu g/m^3$ respectively, starting at a baseline BLL. The associated arithmetic means, for example, for an air lead of 0.15 $\mu g/m^3$ is:

   $4.45 + (0.15)*(4.2) = 5.08$

6. Calculate geometric means by substituting arithmetic means into equation 1 and solving for μ_G.

7. Calculate percent above 10 µg/dL using equation 2 to calculate a Z-score and looking up the result in a table of normal distribution values which can be found in most statistics textbooks.

Summary of Calculations

The arithmetic mean associated with a GM of 3.69 µg/dL and a GSD of 1.84 is 4.45 µg/dL. Assuming a blood lead to air lead slope of 4.2 µg/dL per $\mu g/m^3$, the current contribution of the mean ambient air lead concentration is incorporated in the baseline BLL. A new GM was calculated to incorporate the air concentrations due to the emissions of a facility. A z-score was calculated to determine that emissions from a facility that caused an increase in the air lead of 0.12 $\mu g/m^3$ would result in 7.21 percent of the population being above 10 µg/dL. Geometric means and risk values for Tables 1 and 2 in Chapter II were calculated using this procedure.

Appendix F

Instructions for Estimating Neurodevelopmental Risk from Short Term Operations

Appendix F

Instructions for Estimating Neurodevelopmental Risk from Short Term Operations

In this Appendix, we describe a process for evaluating neurodevelopmental risk for a source planning to operate less than 30 days. An example of a source operating less than 30 days is a fire department training burn on a building with lead paint. The process is similar to a Tier I neurodevelopmental assessment but uses a blood lead/air lead slope of 2.0[1] to represent only the inhalation risk and not the additional risk from long-term accumulation in dust and soil due to deposition from the air.

Using an appropriate air dispersion model, estimate the 30-day average air concentration that the most highly exposed neighborhood would be expected to experience as a result of the emissions. Use Table F-1 to find percent risk of having blood lead levels at or over 10 µg/dL for the exposed population.

[1] This value was recommended by OEHHA for this purpose subsequent to the identification of lead as a Toxic Air Contaminant. It is based on direct inhalation studies of lead exposure in adults.

Table F-1 Percentage and Geometric Mean of Children with Blood Lead Levels ≥ 10 μg/m³ due to Inhalation Only[1] for Various Air Lead Concentrations at Two Exposure Scenarios

Air Lead Concentration (μg/m³)	High Exposure Scenario[2]		Average Exposure Scenario[3]	
	Percent ≥ 10 μg/dL	Geometric Mean BLL (μg/dL)	Percent ≥ 10 μg/dL	Geometric Mean BLL (μg/dL)
baseline[4]	5.1	3.69	1.2	3.13
0.02	5.3	3.72	1.3	3.16
0.06	5.6	3.79	1.5	3.23
0.10	5.9	3.85	1.7	3.30
0.20	6.8	4.02	2.1	3.48
0.25	7.1	4.07	2.3	3.57
0.50	9.7	4.52	3.9	4.00
0.75	12.3	4.93	5.9	4.44
1.0	15.2	5.35	8.4	4.88
1.5	21.5	6.18	14.2	5.75

1. Assumes slope of 2.0 (direct inhalation only).
2. High exposure baseline (GM = 3.69 μg/dL, GSD= 1.84) is from the blood lead study for Butte Montana, Area A.
3. Average exposure baseline (GM = 3.13 μg/dL, GSD = 1.68) is from the unexposed comparison area for the Galena, Kansas Lead Exposure Study.
4. The baseline represents BLLs due to lead in soil, dust, water, food, and background air lead levels.

Appendix G

Statistical Tables for Selecting Sample Size

Appendix G

Statistical Tables for Selecting Sample Size

Table G-1 presents a matrix that can be used to estimate the number of blood lead samples needed to characterize the geometric mean of a log-normal distribution. The sample size is based on a specified level of confidence, a geometric standard deviation you believe the data will have, and the acceptable deviation from the true mean. The table contains matrices for four levels of confidence: 80 percent, 90 percent, 95 percent, and 99 percent. The number to be sampled is found at the intercept of the expected geometric standard deviation and the acceptable multiple of the geometric mean. The acceptable multiple of the geometric mean relates to the desired accuracy. You would use the column for a multiple of 2.0 if it was acceptable for the measured value to be off by as much as 100 percent i.e., if the true value was 5 the measured value could be as much as 10 or as little as 0.

Table G-2 can be used to determine the minimum sample size needed to characterize the number of children with blood lead levels (BLLs) over 10 µg/dL. Table G-2 presents matrices for the same four confidence levels. In the matrix corresponding to the desired level of confidence you would find the intersection between a proportion (p) above 10 µg/dL you believe the data will have, and an acceptable margin of error delta (the deviation from the true value). For example, for a confidence level of 90 percent, believing the fraction of the population with blood lead levels $\geq$ 10 µg/dL is 3 percent (0.03), you would need a sample size of 787 to achieve an accuracy of + or - 0.01 of the true value.

Adjustment for Small Populations

Tables G-1 and G-2 serve to determine the initial uncorrected sample size for studying the geometric mean and the proportion of the population above 10 µg/dL. However, when the population being studied is smaller than the statistically valid sample size, an adjustment is made for a finite population[1].

For Table G-1 use the following:

$n = n_0 (N / (N+n_0))$ where:

- n = the adjusted sample size
- n_0 = the statistically valid sample size from Table G-1
- N = the population size.

[1] Sampling Techniques, third edition Wiley Series in Probability and Mathematical Statistics - Applied, John Wiley & Sons, 1977

For Table G-2 use the following:

$n = n_0 / (1 + (n_0 / N))$, where:

n = the adjusted sample size

n_0 = the statistically valid sample size from Table G-2

N = the population size.

This information is provided to assist districts in the evaluation proposed study plans for blood lead sampling to establish site-specific blood lead distributions.

Table G-1

Confidence Level = 80% 1.2815516

Geometric Standard Deviation	Acceptable multiple (>=1) of geometric mean							
	1.050	**1.100**	**1.200**	**1.300**	**1.400**	**1.500**	**1.600**	**2.000**
1.050	2	0	0	0	0	0	0	0
1.250	34	9	2	1	1	0	0	0
1.500	113	30	8	4	2	2	1	1
1.750	216	57	15	7	5	3	2	1
2.000	331	87	24	11	7	5	4	2
2.250	454	119	32	16	10	7	5	2
2.500	579	152	41	20	12	8	6	3
3.000	833	218	60	29	18	12	9	4
3.250	958	251	69	33	20	14	10	5

Confidence Level = 90% 1.6448536

Geometric Standard Deviation	Acceptable multiple (>=1) of geometric mean							
	1.050	**1.100**	**1.200**	**1.300**	**1.400**	**1.500**	**1.600**	**2.000**
1.050	3	1	0	0	0	0	0	0
1.250	57	15	4	2	1	1	1	0
1.500	187	49	13	6	4	3	2	1
1.750	356	93	25	12	7	5	4	2
2.000	546	143	39	19	11	8	6	3
2.250	747	196	54	26	16	11	8	4
2.500	954	250	68	33	20	14	10	5
3.000	1372	359	98	47	29	20	15	7
3.250	1579	414	113	55	33	23	17	8

Table G-1 (Cont.)

Confidence Level = 95% 1.959964

Geometric Standard Deviation	Acceptable multiple (>=1) of geometric mean							
	1.050	**1.100**	**1.200**	**1.300**	**1.400**	**1.500**	**1.600**	**2.000**
1.050	4	1	0	0	0	0	0	0
1.250	80	21	6	3	2	1	1	0
1.500	265	70	19	9	6	4	3	1
1.750	505	132	36	17	11	7	5	3
2.000	775	203	56	27	16	11	8	4
2.250	1061	278	76	37	22	15	11	5
2.500	1355	355	97	47	28	20	15	7
3.000	1948	510	139	67	41	28	21	10
3.250	2242	587	161	78	47	32	24	11

Confidence Level = 99% 2.5758293

Geometric Standard Deviation	Acceptable multiple (>=1) of geometric mean							
	1.050	**1.100**	**1.200**	**1.300**	**1.400**	**1.500**	**1.600**	**2.000**
1.050	7	2	0	0	0	0	0	0
1.250	139	36	10	5	3	2	1	1
1.500	458	120	33	16	10	7	5	2
1.750	873	229	63	30	18	13	9	4
2.000	1339	351	96	46	28	19	14	7
2.250	1833	480	131	63	39	27	20	9
2.500	2340	613	168	81	49	34	25	12
3.000	3364	882	241	116	71	49	36	17
3.250	3872	1015	277	134	81	56	42	19

Table G-2

Confidence Level = 80%

delta==>	0.005	0.010	0.020	0.030	0.040	0.050	0.100	0.150	0.200
p									
0.01	650	163	41	18	10	7	2	1	1
0.02	1288	322	80	36	20	13	3	1	1
0.03	1912	478	119	53	30	19	5	2	1
0.04	2523	631	158	70	39	25	6	3	2
0.05	3121	780	195	87	49	31	8	3	2
0.06	3705	926	232	103	58	37	9	4	2
0.07	4277	1069	267	119	67	43	11	5	3
0.08	4835	1209	302	134	76	48	12	5	3
0.09	5380	1345	336	149	84	54	13	6	3
0.10	5913	1478	370	164	92	59	15	7	4
0.11	6432	1608	402	179	100	64	16	7	4
0.12	6937	1734	434	193	108	69	17	8	4
0.13	7430	1858	464	206	116	74	19	8	5
0.14	7910	1977	494	220	124	79	20	9	5
0.15	8376	2094	524	233	131	84	21	9	5
0.16	8829	2207	552	245	138	88	22	10	6
0.17	9270	2317	579	257	145	93	23	10	6
0.18	9697	2424	606	269	152	97	24	11	6
0.19	10110	2528	632	281	158	101	25	11	6
0.20	10511	2628	657	292	164	105	26	12	7
0.25	12318	3079	770	342	192	123	31	14	8
0.30	13796	3449	862	383	216	138	34	15	9
0.35	14946	3736	934	415	234	149	37	17	9
0.40	15767	3942	985	438	246	158	39	18	10
0.45	16260	4065	1016	452	254	163	41	18	10
0.50	16424	4106	1026	456	257	164	41	18	10

Table G-2 (Cont.)

Confidence Level = 90%

delta==>	0.005	0.010	0.020	0.030	0.040	0.050	0.100	0.150	0.200
p									
0.01	1071	268	67	30	17	11	3	1	1
0.02	2121	530	133	59	33	21	5	2	1
0.03	3149	787	197	87	49	31	8	3	2
0.04	4156	1039	260	115	65	42	10	5	3
0.05	5141	1285	321	143	80	51	13	6	3
0.06	6104	1526	381	170	95	61	15	7	4
0.07	7045	1761	440	196	110	70	18	8	4
0.08	7965	1991	498	221	124	80	20	9	5
0.09	8863	2216	554	246	138	89	22	10	6
0.10	9740	2435	609	271	152	97	24	11	6
0.11	10595	2649	662	294	166	106	26	12	7
0.12	11428	2857	714	317	179	114	29	13	7
0.13	12240	3060	765	340	191	122	31	14	8
0.14	13030	3257	814	362	204	130	33	14	8
0.15	13798	3450	862	383	216	138	34	15	9
0.16	14545	3636	909	404	227	145	36	16	9
0.17	15270	3818	954	424	239	153	38	17	10
0.18	15974	3993	998	444	250	160	40	18	10
0.19	16655	4164	1041	463	260	167	42	19	10
0.20	17315	4329	1082	481	271	173	43	19	11
0.25	20292	5073	1268	564	317	203	51	23	13
0.30	22727	5682	1420	631	355	227	57	25	14
0.35	24620	6155	1539	684	385	246	62	27	15
0.40	25973	6493	1623	721	406	260	65	29	16
0.45	26785	6696	1674	744	419	268	67	30	17
0.50	27055	6764	1691	752	423	271	68	30	17

Table G-2 (Cont.)

Confidence Level = 95%

delta==>	0.005	0.010	0.020	0.030	0.040	0.050	0.100	0.150	0.200
p									
0.01	1521	380	95	42	24	15	4	2	1
0.02	3012	753	188	84	47	30	8	3	2
0.03	4471	1118	279	124	70	45	11	5	3
0.04	5900	1475	369	164	92	59	15	7	4
0.05	7299	1825	456	203	114	73	18	8	5
0.06	8666	2167	542	241	135	87	22	10	5
0.07	10003	2501	625	278	156	100	25	11	6
0.08	11309	2827	707	314	177	113	28	13	7
0.09	12585	3146	787	350	197	126	31	14	8
0.10	13829	3457	864	384	216	138	35	15	9
0.11	15043	3761	940	418	235	150	38	17	9
0.12	16226	4057	1014	451	254	162	41	18	10
0.13	17379	4345	1086	483	272	174	43	19	11
0.14	18500	4625	1156	514	289	185	46	21	12
0.15	19591	4898	1224	544	306	196	49	22	12
0.16	20652	5163	1291	574	323	207	52	23	13
0.17	21681	5420	1355	602	339	217	54	24	14
0.18	22680	5670	1417	630	354	227	57	25	14
0.19	23648	5912	1478	657	370	236	59	26	15
0.20	24585	6146	1537	683	384	246	61	27	15
0.25	28811	7203	1801	800	450	288	72	32	18
0.30	32268	8067	2017	896	504	323	81	36	20
0.35	34957	8739	2185	971	546	350	87	39	22
0.40	36878	9220	2305	1024	576	369	92	41	23
0.45	38030	9508	2377	1056	594	380	95	42	24
0.50	38415	9604	2401	1067	600	384	96	43	24

Table G-2 (Cont.)

Confidence Level = 99%

delta==>	0.005	0.010	0.020	0.030	0.040	0.050	0.100	0.150	0.200
p									
0.01	2627	657	164	73	41	26	7	3	2
0.02	5202	1300	325	144	81	52	13	6	3
0.03	7723	1931	483	215	121	77	19	9	5
0.04	10191	2548	637	283	159	102	25	11	6
0.05	12606	3152	788	350	197	126	32	14	8
0.06	14968	3742	936	416	234	150	37	17	9
0.07	17277	4319	1080	480	270	173	43	19	11
0.08	19533	4883	1221	543	305	195	49	22	12
0.09	21736	5434	1358	604	340	217	54	24	14
0.10	23886	5971	1493	663	373	239	60	27	15
0.11	25982	6496	1624	722	406	260	65	29	16
0.12	28026	7006	1752	778	438	280	70	31	18
0.13	30016	7504	1876	834	469	300	75	33	19
0.14	31954	7988	1997	888	499	320	80	36	20
0.15	33838	8459	2115	940	529	338	85	38	21
0.16	35669	8917	2229	991	557	357	89	40	22
0.17	37447	9362	2340	1040	585	374	94	42	23
0.18	39172	9793	2448	1088	612	392	98	44	24
0.19	40844	10211	2553	1135	638	408	102	45	26
0.20	42463	10616	2654	1180	663	425	106	47	27
0.25	49762	12440	3110	1382	778	498	124	55	31
0.30	55733	13933	3483	1548	871	557	139	62	35
0.35	60378	15094	3774	1677	943	604	151	67	38
0.40	63695	15924	3981	1769	995	637	159	71	40
0.45	65685	16421	4105	1825	1026	657	164	73	41
0.50	66349	16587	4147	1843	1037	663	166	74	41

Appendix H

Basis and Rationale for Risk Management Levels

Appendix H

Basis and Rationale for Risk Management Levels

1. Risk Management Levels

In the permitting process, the districts make decisions about the need for control technology and whether new sources or modifications to existing sources can be permitted. For this purpose, the district identifies the following risk levels:

1) Toxic Best Available Control Technology (T-BACT) trigger level. This is the risk level at which the district would require a source to install T-BACT on the new source or the new equipment at an existing source.

2) Approvable level. Below this level, the district could approve a new source or modification to an existing source without a Specific Findings Report.

3) Permit denial level. At a risk equal to or above this level, the district would not issue a permit.

For the Hot Spots Program, recommendations are needed for the following risk management levels:

1) Notification level. This is the risk level at which facilities need to notify the exposed population (this could be the same as the significant risk level).

2) Significant risk level. At this level, facilities would be required to implement a risk reduction audit and plan. The risk reduction audit and plan must show how the facility will reduce the risks to below this level within 5 years. The district may lengthen the implementation period up to an additional five years if that additional time will not result in an unreasonable risk and compliance within 5 years is not technically feasible and economically practicable .

3) Unreasonable risk level. Facilities with risks at or above this level must reduce their risks within five years or less. The district may shorten the implementation period if it is technically feasible and economically practicable or if the emissions from the facility pose an unreasonable risk.

2. Basis for Consideration of Risk Management Recommendations

The U.S. Department of Health and Human Services' Centers for Disease Control and Prevention (CDC) has declared that the goal of all lead poisoning prevention activities should be to reduce children's blood lead levels (BLLs) below 10 µg/dL (CDC, 1991). If many children in

the community have BLLs ≥10 µg/dL, communitywide interventions (primary prevention activities) should be considered by appropriate agencies. Interventions for individual children should begin at BLLs of 15 µg/dL. There are a range of recommended actions based on the BLLs. Within the 15-19 µg/dL range of BLLs, a child should be given nutritional and educational intervention and more frequent screening. If BLLs in this range persist, environmental investigation and intervention are recommended. BLLs within the 20-44 µg/dL range trigger a recommendation for environmental investigation and intervention, and a medical evaluation. At BLLs within the 45-69 µg/dL range, the recommendation is for both environmental and medical intervention, including chelation therapy. BLLs over 70 µg/dL constitute a medical emergency and require immediate environmental and medical intervention.

The Department of Toxic Substances Control (DTSC) in the California Environmental Protection Agency has identified a one percent risk of exceeding 10 µg/dL as the "point of departure", i.e., starting point, for decisions about soil clean-up (DTSC, 1996). This might be considered to be analogous to a 1 in a million cancer risk, generally regarded as a level below which no action need be taken. At levels above this, other factors such as land use, technical feasibility, or cost might be considered by DTSC in determining appropriate risk management actions.

The United States Environmental Protection Agency (U.S. EPA) has been directed to establish "screening levels" for lead in soil. The screening level is a level above which site-specific analysis is recommended to establish clean-up goals. In considering what to set as screening levels, the U.S. EPA evaluated soil concentrations which would "pose a risk" to a typical (or hypothetical) child or group of similarly exposed children. The level U.S. EPA considered to "pose a risk" was defined as the concentration at which children had no more than a 5 percent chance of BLLs ≥ 10 µg/dL (U.S. EPA, 1998). In developing the residential screening level, the Office of Solid Waste and Emergency Response (OSWER) applied the U.S. EPA's IEUBK model on a site-specific basis. The model generates a probability distribution of BLLs for a typical child, or group of children, exposed to a particular soil lead level and concurrent lead exposure from other sources. This would be an individual risk for the child in a specific residence. This is an approach that fits well with the purpose of determining whether the soil at a particular location needs to be removed or covered.

The federal Ambient Air Quality Standard (AAQS) for lead was originally set at a level that was designed to prevent 99.95 percent of children from exceeding a BLL of 25 µg/dL, which was at that time the level of concern. Using protection of 99.95 percent of children as a precedent, it might be reasonable to base an assessment of significance on the percentage increase in the number of children expected to have BLLs ≥ 10 µg/dL. However, the data on current blood lead levels in children indicate that this level of protection could not be achieved even if there were no exposure to lead in air because of the other sources of exposure which contribute to children's BLLs.

3. Rationale for the Risk Management Levels for the Simplified Approach

In consideration of the complexity of estimating risk for two different types of health effects using two different averaging times for the dispersion modeling, we are proposing an alternative procedure. In this procedure, the 30-day average air concentration at the point of maximum impact would be compared to air concentrations representing risk management levels. We chose to use the 30-day average at the point of maximum impact because that makes this approach a little more conservative than the detailed approach for most facilities. For the Hot Spots Program, 0.30 $\mu g/m^3$ is recommended as the notification and significant risk level and 0.55 $\mu g/m^3$ as the unreasonable risk level. For permitting, 0.30 $\mu g/m^3$ is recommended as the approvable level and 0.55 $\mu g/m^3$ as the permit denial level. We chose these air concentrations in consideration of the recommended neurodevelopmental risk management levels and the associated cardiovascular risk. They are moderately conservative for all sources except those impacting neighborhoods with a high potential for exposure from other sources. Therefore, we do not recommend their use in areas that would fit the high exposure scenario for neurodevelopmental effects.

4. Rationale for the Risk Management Levels for Neurodevelopmental Effects

The precedents cited, thus far, are based on a calculation of individual risk. This is an appropriate approach for making decisions about whether to clean up the lead at an individual residence or specific location. Risk management for lead emitted to the air from stationary sources differs from risk management for lead in soil. Soil lead is relatively stationary, while lead emitted to the air from a stationary source can increase the exposure of a whole community. Air quality models are used to predict the location and concentration of the resulting lead in the air and are used to predict the point of maximum impact. However, the actual impact of air emissions on exposure cannot be predicted so precisely. In the case of lead, where the contribution from the air lead may be small in comparison to the exposures from other sources, it may be more realistic to evaluate the neurodevelopmental effects for an area rather than for the "maximally exposed individual".

It is possible to calculate the change in the mean BLL for an exposed neighborhood or community but there is little agreement about the significance of "averaged" increases in BLLs. Therefore, we are recommending that the risk (probability) of BLLs $\geq$ 10 µg/dL for the maximum exposure area be evaluated.

<u>Hot Spots Program</u>

The notification level for the Hot Spots Program is recommended at a 5 percent risk of BLLs $\geq$ 10 µg/dL. This is consistent with U. S. EPA's statement that a risk between 1 and 5 percent probability "poses a threat" to children living in a lead contaminated home. The U.S. EPA also concluded that in the context of determining hazardous levels of lead in soil and dust, it was not possible to distinguish between 1 and 5 percent risk due to the uncertainty and variability

associated with relating lead in the environment to blood lead concentrations. To avoid a situation where all sources of lead located in or near a high exposure area would have to make notification, we are recommending an alternative level that allows the consideration of the fraction of the mean BLL the facility contributes. In proposing the level for the facility contribution, we considered the other routes of exposure through water, soil, dust, and food. We believe the air lead should not contribute a disproportionate fraction of the risk. We also must consider that the source doing a risk assessment for the Hot Spots Program will not be the only source of air lead. Notification is recommended to be required only for those with a facility contribution ≥ 10 percent.

The significant risk level for an existing source in the Hot Spots Program is recommended to be set at the 5 percent risk of BLLs ≥ 10 µg/dL. This could present a problem for sources in an area with a high potential for exposure due to other sources. In a high exposure scenario for neurodevelopmental effects, the background risk could be over the 5 percent risk of BLLs ≥ 10 µg/dL. To avoid a situation in which a source would be required to reduce risks due to other sources, it is recommended the facility contribution is not allowed to exceed 10 percent of the mean BLL in the neighborhood.

In considering what might constitute an unreasonable risk for the Hot Spots Program, we found little regulatory precedent. In 1975, U.S. EPA set a maximum contaminant level for lead in water of 0.05 milligrams per liter. This would result in a 20 percent risk of BLLs ≥ 10 µg/dL. This was re-evaluated in 1991 and the U.S. EPA declined to set a maximum contaminant level because there is no known threshold below which lead health effects would not be expected. In consideration of risk levels associated with dangerous levels of lead, the highest probability considered by U.S. EPA was 10 percent. This level would be associated with a probability of 1.6 percent that children would have a blood lead level ≥ 15 µg/dL. The U.S. EPA found this unacceptable and we concur and are proposing a 10 percent risk of BLLs ≥ 10 µg/dL as the unreasonable risk level.

Permit Decisions

Several approaches were considered for setting a T-BACT trigger level. Because there is no safe threshold for neurodevelopmental effects of lead, we considered a zero T-BACT trigger. This approach would require any source seeking a permit for a new source or a modification that would emit lead to install T-BACT. Theoretically, this would require T-BACT for any manufacturer that did small amounts of soldering or casting, for small combustion sources, or for any new firing range. We also considered setting a risk based T-BACT trigger level. For instance, a 1 percent individual risk of having a BLL ≥ 10 µg/dL similar to the DTSC's "point of departure" as discussed earlier. However, we believe a T-BACT trigger should apply to all facilities equally, not depend on whether a new source was proposed for an area with a high potential for exposure due to other sources.

Another approach we considered was a T-BACT trigger level based on an air concentration. An increase of 0.02 $\mu g/m^3$ would double the average exposure based on the population-weighted statewide ambient average concentrations. However, that approach would require a new source that emitted even very small quantities of lead to do air dispersion modeling. A simpler approach for both the sources and the districts would be a T-BACT trigger based on an emission rate. For sources with no stack, an emission rate of 1 pound per month could result in an air concentration of 0.02 $\mu g/m^3$. Using this emission rate as the T-BACT trigger would ensure a consistent level of protection and protection for children in neighborhoods with a high potential for exposure.

In terms of permitting, we believe that if a permit is issued for a source with risks above the significant level, the reasons for issuing the permit should be documented and made public. We further believe there should be a level above which a source should not be issued a permit. The U.S. EPA finds that a probability of BLLs $\geq$ 10 µg/dl between 1 and 5 percent poses a risk. However, they also found that it was not possible to reliably distinguish between a 1 percent and a 5 percent probability. This was due to measurement variability, individual variability and the uncertainties in the modelling process. We considered these factors and the findings of the NHANES study (see Appendix A) that two percent of the children in the western region have BLLs $\geq$ 10 µg/dl. These considerations lead us to recommend a probability of 5 percent as the approvable level. Therefore, if the risk equals or exceeds 5 percent, a decision to permit the source should be accompanied by a justification in a Special Findings Report issued by the district.

We are recommending the permit denial level be a 10 percent probability of BLLs $\geq$ 10 µg/dl. This is consistent with our recommended unacceptable level and was recommended on the basis of similar considerations.

6. Rationale for the Risk Management Recommendations for Cancer

For cancer risk, we are proposing the same risk management levels as in the Risk Management Guidance; a T-BACT trigger of 1 in a million, an approvable level of 10 in a million and a permit denial level of 100 in a million. For the Hot Spots Program, we are proposing a public notification level and significant risk level of 10 in a million and an unreasonable risk level of 100 in a million.

Significance levels for cancer effects have evolved over the past several years. For many districts, less than 1 in a million cancer risk would not trigger use of toxics best available control technology (T-BACT). One hundred in a million, however, is generally considered unacceptable for permitting purposes. Above the 1 in a million level, district new source toxic regulations often require installation of T-BACT. Districts generally require public notification in the Hot Spots Program at a cancer risk of 10 in a million. Individual districts have adopted significant risk levels ranging from 10 to 100 in a million but there is general agreement on an unreasonable risk level of 100 in a million.

Appendix I

Specific Findings and a Specific Findings Report

Appendix I

Specific Findings and a Specific Findings Report[1]

Specific Findings Report

We suggest submitting a Specific Findings Report to the Air Pollution Control Officer (APCO) if the non-cancer and/or cancer risk for a new or modified source is greater than the approvable level. The Specific Findings Report provides the APCO with information upon which he or she can decide whether the permit should be granted.

We believe it is important for the APCO to identify and make available to the public the written findings which support the decision to permit or not permit a source. The APCO may also wish to conduct a public meeting to receive comment from affected parties. Listed below are definitions of key terms and examples of the type of information that may be included in the report.

1. Key Terms

a. Feasible Reduction Measures

Feasible reduction measures are control measures and techniques that are technologically feasible and economically practicable and include, but are not limited to, changes of basic control equipment, product substitution or modification, process modifications, feedstock modifications, operation and maintenance improvements, and enclosing systems or processes to reduce emissions. Feasible reduction measures are different from T-BACT in that they apply to existing permit units. They are similar to T-BACT in that feasibility is determined on a case-by-case basis.

b. Beyond T-BACT

Beyond T-BACT describes any combination of control measures that are needed to reduce a source's potential risk below an applicable criterion value. Beyond T-BACT may include more effective control measures than the measures listed in the definition of T-BACT as well as enforceable limitations on the potential to emit.

[1] Adapted from the ARB's Risk Management Guidelines for New and Modified Sources of Toxic Air Pollutants, July 1993

2. Content

a. Identify pollutants that would be emitted.

The report should identify and quantify the toxic air pollutants that would be emitted from the source.

b. Identify the health impact of the toxic pollutant(s) that would be emitted.

The cancer and non-cancer risk associated with the toxics that would be emitted from the new or modified source should be identified and discussed. The applicant may also wish to discuss potential cancer burden as a measure of communicating the magnitude of the potential cancer risk. As specified in the CAPCOA Air Toxics "Hot Spots" Program Risk Assessment Guidelines, (October, 1993) the permit applicant should also discuss how currently undeveloped areas are "zoned" (i.e. commercial or residential) and use this information to estimate potential health impacts should this area be developed. The applicant may wish to present information on the likelihood that an individual could reside at the point of maximum off-site cancer risk.

c. Discuss the uncertainty in the risk assessment process.

The permit applicant may wish to include information regarding uncertainty in the risk assessment process as described in the chemical health effects documents.

d. Discuss the benefits associated with the new or modified source.

The permit applicant may wish to include information regarding the benefit the new or modified source would provide the local community. Benefits of the source may include the service provided to the community or a decrease in risk compared to risk estimates without the source.

e. Identify federal, state, or local mandates.

The permit applicant may indicate whether there are any existing federal, state, or local mandates that requires modification of an existing source or establishment of a new source. For example, the state's clean fuel regulations may require an existing gasoline station to offer clean fuel for sale. In order to comply, the owner of the gasoline station may have to modify the facility to add a clean fuel pump.

f. Identify multi-media impacts.

The APCO should require the permit applicant to identify the impact the new or modified source may have on media other than air.

g. Discuss the findings of the California Environmental Quality Act (CEQA) document if one was required for the project.

Independent of these guidelines, the APCO must review environmental impact reports (EIRs) that are prepared by the Lead Agency pursuant to the requirements of the CEQA. This document should provide information regarding background, cumulative, and ecological risk. Background risk is the risk associated with the ambient toxic air pollutant levels due to local stationary sources and mobile sources. Cumulative risk is the sum of the risk of toxic air pollutant emissions from local stationary sources within a given area. Ecological risk is the risk to flora and fauna resulting from emissions of toxic air pollutants.

h. Identify sensitive receptors impacted by the new or modified source.

The APCO may require the permit applicant to identify any sensitive receptor locations impacted by the toxic air emissions from the new or modified source. A sensitive receptor location includes, but is not limited to, any hospital, school, or day-care center.

i. Provide a risk reduction plan.

The APCO may require, or the permit applicant may wish to provide, a risk reduction plan identifying all feasible reduction measures to reduce potential risk from the source.

The risk reduction plan should:

i. Identify which processes and activities cause toxic emissions and what portion of the total potential source risk is due to each.

ii. Identify all feasible reduction measures and applicable beyond T-BACT measures for the source type.

iii. Estimate the risk reduction potential of the feasible reduction measures and beyond T-BACT measures.

iv. Estimate how long it would take to implement the feasible reduction measures and beyond T-BACT measures.

v. Determine the technical feasibility and cost-effectiveness of the feasible reduction measures and beyond T-BACT measures for the individual source.

vi. Identify the feasible reduction measures and beyond T-BACT measures that will be implemented to reduce potential risk and a detailed schedule for implementation. If the plan shows that these measures are insufficient to meet the lower risk level, the plan should identify possible reductions in the future.

Appendix J

Regulatory Programs for Lead

Appendix J

Regulatory Programs for Lead

This Appendix presents a summary of past regulatory approaches and actions on airborne lead. It also discusses regulatory programs established to address toxic air contaminants.

Ambient Air Quality Standards

An ambient air quality standard (AAQS) is a regulation designed to protect public health by establishing an allowable air concentration of a pollutant. There are both State and Federal air quality standards for lead. The State AAQS for lead was established in November 1970 following the recommendations of the State Department of Public Health[1]. It was based on health effects data that showed exposure to airborne lead levels above 1.5 micrograms per cubic meter ($\mu g/m^3$) averaged over a 30-day period could result in the accumulation of lead in the body in quantities sufficient to cause impairment of the blood forming system.

The federal standard was set at 1.5 micrograms per cubic meter ($\mu g/m^3$) averaged over a 90-day period. The federal standard was set at a level that would insure that 99.5 percent of children would have a BLL less than 40 micrograms per deciliter (µg/dL). At that time, 40 µg/dL was considered to be an elevated BLL.

As better data on health effects were developed, public health agencies revised downward the BLL of concern. By 1991, the Centers for Disease Control and Prevention (CDC) of the U.S. Department of Health & Human Services, Public Health Service considered 10 µg/dl to be an elevated BLL in children. The CDC recommends community intervention (primary prevention activities by the appropriate agencies) if many children in the community have BLLs at or over this level. An example of a primary prevention activity is clean-up of a site with soil contamination even if it has not been established that the site has contributed to the high BLLs detected. The Office of Environmental Health Hazard Assessment (OEHHA) has identified 10 µg/dl as a level of concern because it is a level at which studies have adequately demonstrated an adverse health effect.

When the Air Resources Board (ARB/Board) reviewed the State AAQS in 1985, changes were made to the measurement methods but the standard was left at 1.5 $\mu g/m^3$ over a 30-day averaging time. The United States Environmental Protection Agency (U.S. EPA) reviewed the federal AAQS in 1990 and did not revise it. It remains at 1.5 $\mu g/m^3$ over a 90-day averaging time.

[1] The State Department of Public Health is now the Department of Health Services (DHS)

The Toxic Air Contaminant Identification and Control Program

Assembly Bill 1807 (1983) established a program for the identification and control of toxic air contaminants. In this program, risk assessment is separated from risk management. Risk assessment is the process of examining the available evidence on health effects associated with exposure to a substance and relating the probability of adverse health effects to a given exposure level. Risk management is the process of evaluating emission sources to determine the need and appropriate degree of regulation, and if necessary, taking action to reduce emissions.

Under the AB 1807 air toxics identification phase (risk assessment), ARB and OEHHA staffs prepare a report for public review that is the basis for the proposed identification of a substance as a toxic air contaminant (TAC). The identification process involves full public participation including numerous comment periods, workshops, meetings with affected industries, a review by the independent Scientific Review Panel (SRP), and consideration by the Board at a formal public hearing.

Once a substance has been formally identified as a TAC, the risk management phase begins. In the risk management process, ARB staff conduct a regulatory needs assessment. A "needs assessment" is an assessment of the need and appropriate degree of regulation for a substance identified as a TAC. Full public participation is also a feature of the risk management process. ARB staff carries out this evaluation in consultation with the districts, affected sources, and the interested public. Typically, the ARB publishes a report that describes the regulatory needs assessment and summarizes staff recommendations for actions.

The following issues are considered to the extent that data can reasonably be made available:

1. current and future anticipated emission rates, levels of human exposure, and the risk associated with those levels;
2. the stability, persistence, transformation products, dispersion potential, and physical and chemical characteristics of the substance when present in the ambient air;
3. the categories, numbers, and relative contribution of present or anticipated sources of the substance;
4. the availability and technological feasibility of control measures, taking into account the effect of control measures on levels of exposure, and recent technological improvements or other actions which emitting sources have implemented in the recent past to reduce emissions;
5. the cost and cost effectiveness of control measures;
6. the availability, suitability, and efficacy of substitute compounds of a less hazardous nature; and
7. the potential adverse health, safety, or environmental impacts of implementing a control measure.

The Board considers the recommendations made in the regulatory needs assessment. When this analysis indicates a need for additional control, staff--subsequent to Board approval--develop, in cooperation with industry and districts, a proposed control measure for consideration by the Board. In a formal hearing, the Board considers public comments, receives public testimony, and acts on the proposal. Once the statewide control measure is adopted, the districts implement and enforce it, or adopt and enforce one at least as stringent.

The status of lead under AB 1807

ARB and OEHHA evaluated lead for identification as a toxic air contaminant (TAC) under the AB 1807 program. The Board approved the listing of inorganic lead as a TAC at a public hearing April 24, 1997. Lead was listed as a TAC for which a threshold exposure level could not be identified. The threshold exposure level is the level below which adverse health effects are not expected to occur. Lead is the first identified TAC for which non-cancer effects with no threshold have been identified. At that hearing, the Board directed ARB staff to develop risk management guidance to assist districts and industry to evaluate the potential health effects of lead emissions.

The OEHHA's review of available health effects data published in the March 1997 "Technical Support Document, Proposed Identification of Inorganic Lead as a Toxic Air Contaminant, Part B Health Assessment" examined and reported on many studies. The OEHHA noted that a recent study specifically focused on determining a threshold was unable to detect one. The ARB, SRP, and OEHHA concur in the conclusion that a "no observed adverse effect level" (NOAEL) cannot be reliably identified for at least three of the health effects of lead: cancer, cardiovascular effects in adults, and neurological impairment in children. Other reviews of health outcomes associated with lead exposure can be found in the U.S. EPA's "Air Quality Criteria for Lead", published in 1986, and "Air Quality Criteria for Lead: Supplement to the 1986 Addendum", published in 1990; the Agency for Toxic Substances and Disease Registry's "Toxicological Profile for Lead", published in 1990 (currently being revised); and the National Research Council's "Measuring Lead Exposure in Infants, Children, and Other Sensitive Populations", published in 1993.

Regulations affecting lead adopted under AB 1807

Following the identification of cadmium as a toxic air contaminant in January 1987, ARB staff developed an airborne toxic control measure (ATCM) for emissions of toxic metals from non-ferrous metal melting operations. The Board adopted the ATCM in January 1993. It is currently being implemented by affected facilities and by the districts. Because lead is emitted from some of the same facilities that the ATCM affects, lead emissions were also reduced as a result of compliance with that regulation. This is because the ATCM requires reduction in emissions of particulate matter, in which cadmium, lead, and other metals occur.

Need for additional regulations to reduce lead emissions

The ARB staff is currently conducting an evaluation of lead sources, emissions, and risk to determine whether additional control measures are needed for lead. The findings of that assessment will determine staff recommendations as to whether additional actions are necessary.

The Air Toxics "Hot Spots" Program

Assembly Bill (AB) 2588 established the Air Toxics "Hot Spots" Information and Assessment Act (Air Toxics "Hot Spots" Program) in 1987. AB 2588 established requirements for facilities to report their emissions of air toxics including lead. The districts review these reports and then prioritize the facilities based on their potential health risk. Risk assessments are performed for high priority facilities. Facilities with risks that exceed district-specified trigger levels must notify the public. To facilitate risk assessment review and improve statewide consistency, the California Air Pollution Control Officer's Association (CAPCOA) published risk assessment guidelines.

In 1992, additional requirements were added through adoption of Senate Bill (SB) 1731. The objective of SB 1731 was to require facilities with significant risks to reduce their risks. SB 1731 requires local air districts to designate significant risk levels. Facilities with risks over the significance level are then required to develop a risk reduction audit and plan describing actions they will take to reduce their risks. SB 1731 also directed OEHHA to develop risk assessment guidelines. Finally, SB 1731 directed the ARB to provide assistance to the districts and smaller businesses. To that end, the ARB has produced a general guideline document for all facilities on how to conduct a risk reduction audit and prepare a risk reduction plan, and source-specific guideline documents for chrome plating, aerospace operations, degreasing operations, and autobody shops.

Other Actions to Reduce Lead Exposure

There have been several regulatory actions taken in the last 10 years which have significantly reduced the public's exposure to lead. Both the ARB and U.S. EPA have acted to reduce lead use in gasoline. The U.S. EPA promulgated a National Emissions Standards for Hazardous Air Pollutants (NESHAP) for Secondary Lead Smelting in 1995 which imposed limits on emissions from stacks and required improved housekeeping and operating procedures to reduce fugitive emissions. The U.S. EPA has promulgated national primary drinking water regulations for controlling lead in drinking water. The U.S. Consumer Products Safety Commission has promulgated limits on lead in consumer products and in paint. These actions have reduced the body burden of lead for U.S. residents. The quantitative effect can be seen in the results of the National Health and Nutritional Examination Surveys (NHANES) which measured blood lead levels at intervals since 1988. See Appendix A for a discussion of the findings of the NHANES studies.

Appendix K

Form for Reporting a Planned Tier II Study to the Childhood Lead Poisoning Prevention Branch

DEPARTMENT OF HEALTH SERVICES
CHILDHOOD LEAD POISONING PREVENTION BRANCH
1515 CLAY STREET, SUITE 1801
OAKLAND, CA 94612
(510) 622-5000

SITE-SPECIFIC ENVIRONMENTAL SAMPLING AT RESIDENTIAL ADDRESSES NEAR A STATIONARY SOURCE FACILITY

Tier II Data for Permit Application

Please complete this information and fax to Environmental Investigations Unit: (510) 622-5002

1. Complete the following Facility information:

NAME OF FACILITY	
ADDRESS OF FACILITY	
CONTACT NAME/TITLE	
CONTACT PHONE/FAX	
LOCAL APC DISTRICT	
APCD CONTACT NAME/PHONE	
LOCAL HEALTH OFFICER	
DATE HEALTH OFFICER NOTIFIED	

2. Complete the following environmental sampling information:

DATE SAMPLING TO BE CONDUCTED	
TOTAL NUMBER OF ADDRESSES TO BE SAMPLED	
TOTAL NUMBER OF SOIL SAMPLES TO BE COLLECTED	
TOTAL NUMBER OF DUST SAMPLES TO BE COLLECTED	
TOTAL NUMBER OF WATER SAMPLES TO BE COLLECTED	
TOTAL NUMBER OF FOOD SAMPLES TO BE COLLECTED	

3. Attach a table that includes the following information:

EACH ADDRESS TO BE SAMPLED
SOIL SAMPLE LOCATIONS
SOIL SAMPLE RESULTS
DUST SAMPLE LOCATIONS
DUST SAMPLE RESULTS
WATER SAMPLE LOCATIONS
WATER SAMPLE RESULTS
TYPE OF FOOD SAMPLED AND RESULTS

4. Explain what steps the Facility will take for environmental results that exceed regulatory levels

5. Explain how the Property Owner will be notified of lead contaminated soil, dust, and water.